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The European research infrastructure for biobanking and biomolecular resources in health and life sciences

ESBB
European, Middle Eastern & African Society for Biopreservation and Biobanking

EUROPE BIOBANK WEEK CONGRESS
13-16 MAY 2025

ORAL PRESENTATIONS

Abstracts

Produced by the Europe Biobank Week Programme Committee and BBMRI-ERIC's Department of Outreach, Education and Communications

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KN1. Keynote One

O1. The need for courageous leadership in science and health in challenging times

Prof. Walter Ricciard (1)
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Abstract

In an era marked by unprecedented global challenges, including pandemics, climate change, social inequities, technological and geopolitical disruptions, the need for courageous leadership in science and health has never been more critical.

This presentation explores the essential qualities of courageous leadership, including integrity, vision, resilience, and the ability to make difficult decisions under pressure. It highlights how leaders in science and health must not only respond to crises but proactively shape systems and policies that promote equity, transparency, and innovation.

Drawing on case studies from recent health emergencies and scientific breakthroughs, this discussion emphasises the importance of collaboration, ethical accountability, and adaptability. Ultimately, it calls for a new generation of leaders who are willing to challenge the status quo, advocate for evidence-based solutions, and inspire collective action toward a healthier and more resilient future.

KN1. Keynote Two

O2. Bringing the benefits of biobanking closer to the people

Prof. Dr. Lili Milani (1)
(1) University of Tartu

Abstract

Large biobanks have set a new standard for research and innovation in human genomics and the implementation of personalised medicine. The Estonian Biobank was founded 25 years ago, and its biological specimens, clinical, health, omics, and lifestyle data have been included in over 800 publications. What makes the biobank unique is its translational focus, with active efforts to conduct clinical studies based on genetic findings and to explore the effects of return of results on participants.

In June 2024, the biobank opened an online portal called MyGenome for all its participants. The portal contains personalised information on genetic and cumulative risk for type 2 diabetes and coronary artery disease based on polygenic risk scores and other risk factors. The reports include interactive graphs that allow participants to explore how their risk can change with lifestyle modifications. The results section also contains fun facts such as caffeine metabolism profiles and ancestry reports. Over 100,000 participants have logged in to the portal and signed the dynamic consent specifying which areas they wished to receive results in. The keynote will provide an overview of the portal and the feedback received from the participants that completed the questionnaires at the end of each report.

EC. Ethics Café

O3: TBC

TRACK 1. Navigating the Future of Biobanks: Challenges and Innovations

3A: One Health: Non-human biobanking

Establishing One Health Exploratories: A Holistic Approach to Integrative Health Monitoring

by Dominic Bläsing | Markus Ulrich | Sebastien Calvignac-Spencer | Filipe Dias | Leonce Kouadio | Lorenzo Lagostina | Kathrin Nowak | Elangwe-Milo Sarah-Matio | Katharina Schaufler | Franziska Stoek |

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One Health | Helmholtz Institute for One Health | Helmholtz Institute for One Health | Helmholtz

Institute for One Health | Helmholtz Institute for One Health | Helmholtz Institute for One Health | Helmholtz Institute for One Health

Topic: 3A: One Health: Non-human Biobanking

Presenter Name: Dominic Bläsing

Keywords: Biodiversity, Human Cohort Study, One Health Exploratory, One Health Monitoring, Pandemic Preparedness

The Helmholtz Institute for One Health (HIOH) is developing a network of One Health Exploratories—spatially defined research areas designed for systematic, longitudinal monitoring of key indicators spanning human, animal, and environmental health. These exploratories will enable a participatory, integrated, transdisciplinary approach to better understand disease emergence, antimicrobial resistance, and ecosystem health dynamics. The first extensive sampling campaign is scheduled to begin in 2026, with ongoing long term HIOH activities (10 years+) and final preparatory projects ensuring a seamless launch of this ambitious initiative.

Current preparatory efforts include:

A) Networking and methodological integration: Building on expertise from previouspopulation-based studies to optimize study designs, ensure data harmonization, and facilitate interinstitutional collaboration.

B) Public engagement and participatory research: Involving all stakeholders from nationaland regional authorities to local authorities and communities in order to guarantee ethical study implementation, informed consent, and culturally sensitive methodologies.

C) Multifaceted sampling and diagnostic pipelines: various projects have been initiated todevelop standardized protocols for environmental sampling, small-mammal monitoring, and optimized diagnostic workflows. Additionally, clinical surveillance programs, a human cohort study protocol, and integrated approaches for monitoring domestic animals are under development.

A key aspect of this initiative is compliance with international biobanking regulations and ethical considerations. In adherence to equitable research practices and national sovereignty over biological resources, aliquots of collected samples will be stored both in the partner countries and in Germany. This ensures data accessibility while respecting national policies, benefit-sharing principles, and the

FAIR, CARE, and TRUST frameworks governing ethical biobanking.

How to “do” the Nagoya Protocol: common misconceptions and practical advice for access and benefit-sharing compliance

by Davide Faggionato | Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures GmbH

Topic: 3A: One Health: Non-human Biobanking
Presenter Name: Davide Faggionato
Keywords: Nagoya protocol

The Nagoya Protocol (NP) on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (ABS) has been in force for over a decade and governs the access to and exchange of genetic resources (GR) between countries and researchers.

Biobanks and collections of non-human genetic resources play a key role in long-term preservation, and the responsible distribution of genetic resources (i.e. microorganisms, plants, animals), playing a critical role in supporting compliance with the NP. In turn, compliance with the Nagoya Protocol, promoting equitable access and sustainable sharing of genetic resources, is fundamental to the One Health approach, as it ensures transparent transnational collaboration in biodiversity stewardship, a prerequisite for safeguarding the global and interconnected health of humans, animals, plants and ecosystems.

Nevertheless, despite years of NP implementation, a significant lack of awareness and uncertainty still persists among researchers regarding its application. Common misconceptions include the belief that ABS is impossible, that researchers from countries non-signatories of the NP, like the US, are exempt, or that the country of origin of a microbiological genetic resource is determined by where it is cultivated and analyzed.

We will address these and other misconceptions and clarify best practices for NP implementation, highlighting common challenges in accessing genetic resources from provider countries. Additionally, we will provide guidance on compliance for researchers, biobank and collection managers as they navigate ABS requirements.

Advancing One Health and Non-Human Biobanking: The Future of the Swiss Network

by Joséphine Uldry | Sabine Bavamian | Lou Walder-Ferraton | Christine Joye | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform

Topic: 3A: One Health: Non-human Biobanking
Presenter Name: Joséphine Uldry
Keywords: Environmental, Nagoya Protocol, Non-human biobanks, One Health, Pathogens, Quality, Veterinary, data management, network

One Health approach considering the health of humans, animals and environment in a holistic way to address threats, has gained significant interest in the scientific community in recent years. Biobanks are emerging as key actors in evaluating the interconnectedness of the living components, by facilitating the collection and storage of biological materials and associated data from various organisms, all at the same location.

In this context, a network of biobanks spanning human and non-human fields is necessary to establish a common language for providing the needed samples and data, to enable highquality research. From its creation in 2015 as a research infrastructure funded by the Swiss National Science Foundation, Swiss Biobanking Platform (SBP) has in its mission the essential role of coordinating both human and non-human biobanking nationally.

The SBP network currently encompasses non-human biobanks that store veterinary materials, pathogens affecting humans and animals, and microbiomes and bacteria from human medical samples. As an initial measure, SBP has introduced custom datasets specific to microbiology and veterinary biobanks (liquid and tissue). Guidelines were also provided to non-human biobanks on applying the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, accompanied by specific datasets. Looking ahead, SBP aims to expand its network by integrating biobanks from the environmental, food and natural history museum domains. Sharing expertise in quality and data management from human biobanks, along with fostering synergies, is fundamental to bridging collaborations with other research partners and national initiatives.

BRC4Env, the French Biological Resource Centre for Environment

by Sylvia Bruneau | Emmanuelle Artige | Céline Faivre-Primot | Frédéric Marchand | Samuel Mondy | Céline Ratié | Dirk Redecker | Nicolas Ris | Sylvie Warot | Christian Mougin1 | UMR 1402 ECOSYS

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Topic: 3A: One Health: Non-human Biobanking
Presenter Name: Sylvia Bruneau
Keywords: Environment monitoring, One Health approach, agro-ecological transition, biodiversity, pollutants, soil microbiome

BRC4Env is the environmental pillar of the French Research Infrastructure RARe. (https://www.agrobrc-rare.org/), led by the French National Institute for Agriculture, Food and Environment (INRAE). BRC4Env manages various biological and genomic resources for agroecological research and environmental health.

Since 2018, France has been engaged in the world challenge of Global Soil to preserve soil fertility. BRC4Env network includes the European Soil Conservatory, used to monitor soil health, from microbiome to pollutants. BRC4Env aims also at monitoring biodiversity in the aquatic ecosystem, holding 460.000 ichthyological samples collected for 50 years and, the terrestrial ecosystem with one million arthropod specimens collected worldwide for over a century. BRC4Env manage also living

collections of parasitoid Trichogramma and arbuscular mycorrhizal fungi used in biocontrol and as biofertilizers, respectively.

The catalogue of BRC4Env resources is accessible at the portal https://urgi.versailles.inrae.fr/brc4env/ and corresponding data (genomic, phenotypic, ...) are available for academic and socio-economic researchers. BRC4Env-linked publications are accessible at https://hal.inrae.fr/BRC4ENV.

BRC4Env aims to provide a strategic delivery for academic and applied research in environmental health, support the agroecological transition and unravel mechanisms at stake in the adaption of species to climate and environmental changes such as pollution, emergence of pathogens or resistance.

Reference: Mougin C. *et al.* BRC4Env, a network of Biological Resource Centres for research in environmental and agricultural sciences. *Environ Sci Pollut Res* **25**, 33849–33857 (2018). https://doi.org/10.1007/s11356-018-1973-7

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4A: Clinical biobanks: Bridging research and patient care

Infectious diseases tissue biobanking and biodata management of the German Center for Infection Research – a key infrastructure for multiple research approaches

by Tilman Pfeffer | Isabel M. Klein | Peter Schirmacher | German Center for Infection Research (DZIF),
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Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care
Presenter Name: Tilman Pfeffer
Keywords: German Center for Infection Research (DZIF), Infectious research, tissue biobanking

The DZIF Tissue Bank, as part of the German Center for Infection Research (DZIF) Translational Infrastructure Bioresources, Biodata and Digital Health (TI-BBD), supports multiple infectious research projects and various studies with biosamples, biodata and latest technologies.

Located at the Institute of Pathology Heidelberg, the DZIF Tissue Bank has access to >800.000 biosamples in the pathological archive. Its support of >125 infectious research projects results in >40 high-ranked publications since 2013. As accredited for DIN EN ISO 20387, the DZIF Tissue Bank is the central national infectious disease tissue biobank. The offered services (biosample-storage, IHC, IF, chemical stainings, Tissue-Micro-Array assembly, nucleotide extraction) following SOPs and therfore guarantee for a maximum of quality, safety, and reproducibility. Besides, consulting, training and connecting biobanking services with state-of-the-art biodata processing facilities in the DZIF TI-BBD are of particular importance.

Significant achievements encompass the contribution, coordination and fully integration of the unique COVID-19 autopsy registry in Baden-Württemberg, Germany, into the DZIF Tissue Bank, where we store over 12.000 COVID-19 biosamples (cryo and FFPE) and maintain the specifically established web-

based autopsy registry. Furthermore, significances of invasive fungal infection (IFI) in organ transplantation (together with the transplantcohort of DZIF) are investigated.

Quality assured tissue biobanking as by DZIF Tissue Bank, is a relevant central national research infrastructure and significantly contributes to infectious research. The DZIF Tissue Bank enhances the efficiency of biobanking for infectious diseases research and as part of the DZIF TI-BBD, its biosamples and metadata management are of high relevance.

Advancing Personalized Medicine and Public Health

by Dr. Marwa Eldeeb | Qatar Biobank

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care

resenter Name: Dr. Marwa Eldeeb Keywords: Qatar biobank; precision medicine; biobanking; health care; incidental findings.

The Qatar Biobank (QBB) aims to collect comprehensive lifestyle, clinical, and biological data from up to 60,000 Qatari citizens and long-term residents aged 18 and above. Participants are invited to return every five years to monitor disease development, investigate its causes, and identify risk factors specific to the Qatari population. This presentation highlights the significant impact of QBB in identifying and reporting incidental findings (IFs).

Consented participants undergo a thorough collection of clinical, genetic data and imaging data from MRI scans, and other at QBB facilities. QBB has established a comprehensive framework to manage Ifs, ensuring ethical considerations, participant engagement, and data integrity. QBB reports IFs found in MRI scans, laboratory results, and actionable genetic findings, facilitating timely referrals. Participants receive feedback from QBB physicians and are referred to appropriate healthcare services.

Case presentation:
On May 7, 2024, a 54-year-old female participant attended her MRI appointment at QBB. During the imaging, the radiographer detected an abnormality and notified the medical office. The attending physician identified the mass as a meningioma. After completing the MRI, the QBB physician issued an emergency referral, explained the diagnosis to the participant, and advised her to go to the emergency department immediately. The participant promptly went to HMC, where a contrast MRI confirmed the diagnosis. On May 12, she underwent surgery to remove the tumor and is now recovering well.

Conclusions:
Qatar Biobank's (QBB) comprehensive framework for managing Ifs significantly enhances personalized medicine by ensuring early disease detection leading to improved health outcomes and well-being.

Biobanking from a pharmaceutical company perspective

by Sarah Preisler | Novo Nordisk A/S

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care

Presenter Name: Sarah Preisler

Keywords: Biobanking, clinical trials, governance, operations, pharmaceutical industry

Novo Nordisk is a global pharmaceutical company with over 100 years of experience in developing medicines for patients with diabetes, obesity and other chronic diseases.

While conducting clinical trials to assess the safety, efficacy, and potential benefits of new drug candidates, Novo Nordisk also recognizes the pivotal role of collecting biosamples from the patients for biobanking purposes in order to advance further biomedical research and improve patient care.

Biobanking in Novo Nordisk serves purposes such as facilitating exploration of novel biomarkers and validation of drug targets, and it enables retrospective analyses to uncover new insights and support the continuous improvement of existing treatments. Collection of longitudinal samples additionally enables study of disease progression and treatment response over time.

The samples in the Novo Nordisk biobank are obtained as part of clinical trials from all therapy areas in scope of Novo Nordisk. The process of handling the biosamples is designed to ensure the integrity and traceability of samples while adhering to the highest ethical and regulatory standards.

The presentation sheds light on the operational and governance aspects of driving biobanking with clinical samples at Novo Nordisk, more specifically how the samples are collected and stored, as well as the process of using them for research purposes.

Five Years of Insights from the GEICO Registry (GEICO 81-T): a Virtual Gynecological Cancer Clinical Registry with Decentralized Biospecimen Collection

by Lopez-Guerrero, JA | Marquina, G | de Juan, A | Churruca, C | Barretina-Ginesta, MP | Pertejo, A | de Sande, L | Esteban, C | Herrero, A | Quindós, M | Caballero, C | Masvidal, M | Legerén, M | Martínez-del

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Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care

Presenter Name: Jose Antonio Lopez-Guerrero

Keywords: Clinical Registry,

Collaborative Network, data harmonization,

stakeholder engagement

Introduction

In 2019, the Grupo Español de Investigación en Cáncer Ginecológico (GEICO) launched a prospective virtual clinical registry (VCR) in collaboration with decentralized biobanks affiliated with the Spanish Platform of Biomodels and Biobanks (PTBB-ISCIII). This initiative aims to collect real-world data and biological samples from gynecological cancer patients to improve patient management, enhance diagnostic and therapeutic strategies,

and provide high-quality resources for future research. Here, we present the status of the GEICO VCR after five years and discuss its main challenges.

Material & methods
The GEICO-VCR is an observational, prospective, multicenter study involving 48 hospitals across Spain with PTBB-ISCIII-affiliated biobanks. Clinical data are recorded in the registry, structured into four cohorts: Ovarian Cancer (OC), Endometrial Cancer (EC), Cervical Cancer (CC), and Gestational Trophoblastic Disease (GTD). Data are electronically stored in seven datasets, ensuring comprehensive tracking. The registry also promotes biospecimen collection.

Results
Since March 2019, 2,411 patients have been enrolled: 1,059 (44%) OC, 939 (39%) EC, 375 (16%) CC, and 38 (1%) GTD. A total of 786 (32.6%) biospecimens have been collected, including formalin-fixed paraffin-embedded (786) and frozen tissues (89); serum (223), plasma (240), and buffy coat (37). Key challenges include coordination among specialists, researcher commitment, sample quality, and independent GEICO-PTBB-ISCIII operations.

Discussion and conclusions
While the GEICO-VCR presents a valuable model for collecting clinical data and biospecimens, it faces several limitations that make its success lower than initially expected. The knowledge of these limitations is helping us to design action plans that seek to encourage participation in the GEICO-VCR.

5A: Rare Disease Biobank Insights

“Biobanks and rare diseases in social networks. Perspective from convergent ethics” - Leading case 2023-2025”

by Liliana Virginia Siede | Universidad de Buenos Aires

Topic: 5A: Rare Disease Biobank Insights
Presenter Name: liliana virginia Siede
Keywords: Biobanks, Convergent ethics, rare diseases, social networks

Objective of the Study This article analyzes and reflects on the impact on social networks of the significance of rare diseases and Biobanks based on listening to the opinions and perceptions of digital citizens who participate in X ex Twitter, and other networks that cover their concerns, expectations, emotions and feelings. The purpose is to access the opinions of the authors and identify their perspectives, how they conceive the subject of study, which actors and general problems they are associated with and what future demands they express.

Method: Quantitative-qualitative method (digital ethnography) that allows to see the impact of the topic on social networks from keywords, comparing the data obtained, such as main influencers, content with greater engagement, concerns and emotions.

Results: They show the lack of communication with the population that promotes science, from its impact on public opinion, which indicates the limited use of these technological tools by scientific work teams.

Conclusions: The application of new technologies by Biobanks in the new communication spaces adopted by society, have great potential for their development. In this case, it is observed that social networks

can be very useful to promote information and education in society that generates an impact on public opinion such as generating greater awareness, participation not only of patients, families and communities but of society in general.

Rare Disease Moonshot – Scaling up Public-Private Partnerships to Accelerate Research in Rare Diseases

by Roseline Favresse | Magda Chlebus | Marta del Álamo | Daria Julkowska | Cécile Ollivier | Manuela Pausan | Adrien Samson | Anton E. Ussi | Mathieu Boudes | Victor Maertens | EURORDIS – Rare Diseases

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Topic: 5A: Rare Disease Biobank Insights

Presenter Name: Roseline Favresse

Keywords: diagnostic research, public-private partnerships, rare disease

The Rare Disease Moonshot initiative aims at transforming the rare disease landscape through collective expertise and public-private partnerships (PPPs) at the core of its mission. With more than 300 million people worldwide affected by rare diseases—many undiagnosed or untreated—the initiative unites stakeholders to drive systemic change and accelerate scientific breakthroughs.

The Rare Disease Moonshot identified three areas of action where PPPs can add most value: (i) Enhancing clinical trials for rare diseases by addressing challenges such as small patient populations, dispersed expertise, and complex regulatory pathways. The initiative advocates for innovative trial designs, regulatory science advancements, and infrastructure development. Biobanks can support in patient stratification and trial efficiency.

(ii) Optimising diagnostic research aimed to shorten the 'diagnostic odyssey' throughincreasing accuracy, improving time to diagnosis and ensuring accessibility to diagnostic tools. Advances in genomics, multi-omics technologies, and deep phenotyping are essential in discovering novel biomarkers. Biobanks can support biomarker discovery and validation, through access to diverse rare disease collections available for research. Integrating AI and ML models can further enhance diagnostic capabilities, enabling early and accurate disease identification.

(iii) Accelerating translational research requires overcoming barriers hindering the progressof scientific findings to clinical application. The initiative promotes cross-sectoral accelerators, technology transfer enhancements, and early regulatory engagement to facilitate the journey of scientific discoveries from bench to the bedside.

Together, through collaboration and shared commitment, Rare Disease Moonshot aims at tackling the challenges of rare diseases and improve outcomes for millions of patients globally.

Gap analysis of 4-year data in the Dutch Dystrophinopathy Database

by Y.D Krom | N. Ikelaar | J. Bongers | R. Hoek | N.M. Van de Velde | R.R. Snijder | S Houwen-van Opstal |
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Topic: 5A: Rare Disease Biobank Insights
Presenter Name: R.R. Snijder
Keywords: Becker muscular dystrophy, Duchenne muscular dystrophy, FAIR, real-world data, registry, trial readiness

Duchenne and Becker muscular dystrophy (DMD and BMD) lack curative treatments. Registers can facilitate therapy development, aid in studying epidemiology, assess trial feasibility, collect real-world data (RWD), perform post-market surveillance, and collaborate in (inter)national initiatives.

For all these purposes, it's crucial to gather high-quality, interchangeable, and reusable data from a representative population. The Dutch Dystrophinopathy Database (DDD), a national registry for patients with DMD or BMD, and females with pathogenic DMD variants, is used to collect these vital data.

The design of DDD is governed by FISMA [*see other poster*] that ensures interoperable and reusable data adhering to international standards and allows for RWD capture without posthoc curation by data stewards.

Here, we present a gap-analysis of standardized clinical data collected in DDD in patients diagnosed with DMD. DDD coverage was high: 85% of DMD patients at Radboudumc and LUMC registered.

- Data on genetics, corticosteroid use,
- and ambulatory status was 100% captured.

Missing data reveals an average of 5.4%.

Most gaps were a result of the transitioning from pediatric to adult care and referral patterns within the Dutch healthcare system. For example, patients with an FVC<60% are seen by home ventilation centers. Only minor gaps arose from center to center variability.

DDD provides consistent coverage of long-term DMD patient and high-quality RWD in the Netherlands, supports trial readiness, post-marketing surveillance, and effective data use using a multicenter design that is scalable to other neuromuscular disorders.

Advancing the IMGGE RD Biobank through BRIDGING-RD Project: Achieving full interoperability of genetic and phenotypic data to enhance participation in transnational research and innovation for human health

by Komazec J. | Andjelkovic M. | Klaassen K. | Skakic A. | Ugrin M. | Pavlovic S. | Nordgren A. | Lindstrand A. | Kjellqvist S. | Matic Lj. | Stojiljkovic M. | Institute of Molecular Genetics and Genetic Engineering, University of Belgrade, Belgrade, Serbia | Institute of Molecular Genetics and Genetic
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Topic: 5A: Rare Disease Biobank Insights
Presenter Name: Komazec J.
Keywords: Keywords: rare diseases, Serbia, biobank

Introduction: The Institute of Molecular Genetics and Genetic Engineering (IMGGE) RD Biobank, established one decade ago as part of the Horizon Europe Project SERBORDISinn, collects samples from patient with rare diseases (RD). Currently, over 7.000 samples from patients with confirmed or suspected RD have been gathered. Given the growing number of samples, there is a need to upgrade the IMGGE RD Biobank. The goal is to implement best practices that will enhance data handling capabilities and ensure the biobank meets evolving standards for efficiency, data quality (both genetic and phenotypic), ethics and interoperability.

Material & Methods: A collaboration between IMGGE and Karolinska Institutet was established through Horizon Europe Project BRIDGING-RD (2024-2027). This initiative involves personnel training, staff and expert exchanges, and the creation of a report with recommendations for improving the biobank's current operations.

Results: Recommendations will focus on optimizing the handling, storage, and management of biobank samples, along with developing improved SOPs for genetic and phenotypic data quality and interoperability. Ethical, legal and other formal aspects of biobanking will be assessed as well.

Conclusion: Implementing these recommendations will significantly enhance the IMGGE RD Biobank's research potential, enabling more comprehensive studies on RD. This effort will also support the continued expansion of the biobank's sample collection, ultimately transforming it into a formally structured resource for collecting, storing and using biological samples for long-term research. Furthermore, our project will likely set the example that may influence practices of biobanking and ethical legislation in this area in Serbia.

This work was supported by BRIDGING-RD,HORIZON-WIDERA-2023-ACCESS-02, N°101160079

7A: Green Biobanking: Paving the Path to Sustainable Practices

How to calculate your Biobanks carbon footprint?

by Monika Valjan | Veronika Perz | Sabrina Kral | Petra Tauscher | Biobank Graz, Medical University of
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Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices
Presenter Name: Monika Valjan
Keywords: CO2, carbon footprint, emissions, environmental sustainability

Introduction:
Climate change, driven by greenhouse gas emissions impacts on various aspects of life, such as food production, water availability, and the (re)emergence of diseases. The biobanking field encompasses a range of activities that contribute to greenhouse gas emissions. Understanding the carbon footprint of these activities, how they can be measured, and subsequently reduced, is of significant importance.

Material & Methods:
Biobank Graz, a partner of BBMRI.at, performed intensive literature research and consulted with experts in the field of sustainability, with a focus on carbon footprint calculations. Based on the "Greenhouse Gas Protocol" to prepare a carbon footprint calculation, the biobank processes and its resulting CO_2 emissions, were divided into 3 scopes: direct emissions, emissions of purchased energy and indirect emissions.

Results:
After reflecting our processes, we believe that the most important emissions in Biobank Graz come from 1) energy demand (e.g. electricity), 2) resources that are needed in large amounts (e.g. liquid nitrogen, labware, IT-devices), 3) mobility of employees and 4) refrigerants.

Discussion & Conclusion:
The determination of energy and resource requirements for biobanking activities along with the resulting carbon footprint is the first important step towards achieving more efficient and sustainable biobanking. This process allows biobanks not only to reduce e.g. the energy demand of specific equipment and Infrastructure but also to compare the environmental impacts of certain processes, all while reducing costs.

Green Biobanking: gaps and challenges

by Saba Abdulghani | Grazia Malovan | Kurt Zatloukal | Cornelia Stumptner | Jens K Habermann | BBMRI-ERIC | BBMRI-ERIC | Medical University Graz | Medical University Graz | BBMRI-ERIC

Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices
Presenter Name: Saba Abdulghani
Keywords: environmental practices, green biobanking, sustainability

Introduction:
Biobanks play a crucial role in biomedical research, yet their environmental impact remains a concern. The Green Biobanking Environmental Challenges and Best Practices Survey, conducted under the EvolveBBMRI project, aimed to assess sustainability practices across European biobanks.

Materials and Methods:
The survey involved 50 biobanks from 12 BBMRI member/observer countries. Data were collected on energy sources, waste management, water conservation, and sustainability planning. Quantitative analysis was used to identify gaps and challenges in implementing eco-friendly practices.

Results:
Initial findings revealed that more than half of the participating biobanks use renewable energy, while 41% still depend on fossil fuels, resulting in high carbon footprints. There was also a significant lack of formal water conservation measures and effective non-hazardous waste management. Although more

than half of the participating biobanks reported engagement in recycling programs, comprehensive material reuse programs are still limited. Additionally, the majority of the participating biobanks have no long-term sustainability strategies.

Discussion and Conclusion:
The survey identified key barriers such as insufficient funding, restricted access to sustainable products, and inadequate staff training. The study highlights the urgent need for strategic planning, enhanced training, and increased funding to foster sustainable practices in biobanking. By addressing these challenges, biobanks can lead the way in integrating environmentally responsible practices in the biomedical sector.

Quantum-Proofing Your Data: The Future of Cybersecurity for biobanks and scientific data

by Werner Strasser | Fragmentix

Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices
Presenter Name: Werner Strasser
Keywords: quantum computers

As quantum computers become more powerful, current online data environments will become increasingly insecure. State actors and cybercriminals are already exploiting this emerging technology, adopting a "collect now, decrypt later" approach. To safeguard against these threats, new standards such as Post-Quantum Cryptography (PQC) must be introduced to replace traditional encryption protocols.

However, most innovations like PQC only protect data in transit, leaving "data at rest" vulnerable. To address this, the cryptographic principle of "secret sharing" can be employed, storing sensitive data federated across multiple locations and concealing fragment locations. This approach ensures that even if one storage provider is compromised, no actual information is exposed.

This speech will explore the looming threat of quantum computing to cybersecurity and discuss innovative solutions such as PQC, QKD and secret sharing. We will examine the current state of quantum-proofing technologies and outline strategies for protecting sensitive data in a post-quantum world. Join us to learn about the future of cybersecurity and how to safeguard your organization's most valuable assets against the emerging threats of quantum computing. Discover the latest developments in quantum-resistant cryptography and take the first step towards securing your data in a rapidly changing cyber landscape.

VIVA: A Cutting-Edge Biobank for Translational Research and Sustainable Development

by Minghetti L | Brazzale G | Carabotta G | Ferrari A | Mainardi M | Marangon G | Monterosso D | Napolitano M | Sorrentino E | Taranto M | Turetta S | Viezzoli T | Istituto Superiore di Sanità, Rome , Italy | SIAD Group, Bergamo , Italy | Istituto Superiore di Sanità, Rome , Italy | SIAD Group, Bergamo , Italy | SIAD Group, Bergamo , Italy | SIAD Group, Bergamo , Italy | Istituto Superiore di Sanità, Rome , Italy | Istituto Superiore di Sanità, Rome , Italy | Istituto Superiore di Sanità, Rome , Italy | Istituto Superiore di

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Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices
Presenter Name: Luisa Minghetti
Keywords: Sustainable Practices; Innovation; one health

Introduction

The “VIVA” biobank is an ambitious project establishing high standards for biological sample processing and storage while supporting sustainable development goals. The project is based on a technical sponsorship between the Istituto Superiore di Sanità (ISS), the Italian National Institute of Health, and the SIAD Group, which includes Medigas, a company with twenty years of expertise in designing laboratories for sample preservation.

Materials and Methods

Spanning 700 square meters, the VIVA biobank will store up to 5,000,000 biological samples in two storage areas for historical samples and new collections and a third one as disaster recovery unit to back up other Italian biobanks. State-of-the-art laboratories will be established providing safe and comfortable areas for biobanking activities. With a modular and flexible spaces to address future expansion/needs, it will ensure comprehensive security systems to protect sample and data integrity and operator safety. Sustainability will be ensured through innovative energy-efficient systems, the use of renewable resources and intelligent management technologies designed to minimize environmental impact.

Expected Results

VIVA biobank aims to enable translational research, transforming basic research into clinical applications and supporting studies on human, animal and environmental origin , adopting the integrated approach of “One Health” characterizing ISS research. By promoting innovation and sustainability, the biobank will advance prevention, diagnosis and therapy enhancing public health.

Conclusion

VIVA biobank redefines biobanking by integrating operator feedback throughout its design. The project exemplifies sustainable infrastructure, aligning with global objectives for health, innovation, economic growth and environmental sustainability.

8A: The Transformative Role of Biobanks in Public Health

Biobanking in the German National Cohort (NAKO): A Pivotal Resource for Epidemiological Research

by Nicole Großkinsky | Sabrina Schmitt | Jennifer Hilger-Kolb | Barbara Bohn | Lennart Palm | Matthias Nauck | Esther Breunig | Tobias Pischon | Tamara Schikowski | Peter Schirmacher | Wolfgang Lieb | Julia

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Topic: 8A: The Transformative Role of Biobanks in Public Health
Presenter Name: Nicole Großkinsky | Dr. Sabrina Schmitt
Keywords: Biobanking, Biosamples, Cohort Study, Epidemiological Research, German National Cohort (NAKO)

Introduction
Biobanking plays a central role within the German National Cohort (NAKO), Germany's largest population-based cohort study, investigating risk factors and pathways of many common diseases, including cancer, diabetes, cardiovascular, pulmonary, and neuropsychiatric diseases.

Materials and Methods
Between 2014 and 2019, over 205,000 participants aged 20–74 were recruited from the general population across 18 study centres in Germany. Regular 5-year examinations include interviews, questionnaires, biomedical assessments, whole-body MRI, and biosample collection (blood, stool, urine, saliva, and nasal swabs). Participants are followed up for incident diseases via questionnaires and linkage to cancer registries, health insurance claims, municipal registries, and mortality follow-up. One-third of biosamples are stored locally, two-thirds at the Central Biorepository (Helmholtz Centre, Munich). The Tumor Tissue Bank (TTB) in Heidelberg collects FFPE tumor samples from NAKO participants diagnosed with cancer.

Results
In total approximately 18.9 million biospecimens are currently stored at the Central Biorepository, and 8.4 million at the local biorepositories of the study centres. Since 2020, approximately 33,500 samples have been provided for research. A TTB pilot study archived 52 tissue samples, ensuring quality-assured storage workflows.

Discussion and Conclusion
In addition to detailed health-related data, a broad spectrum of biosamples is being collected from each participant. These biosamples represent an invaluable resource for advancing health research. Future efforts will integrate multi-omics approaches, to enhance insights into genetic, molecular, and environmental interactions. National and international researchers can access NAKO's data and biosamples via TransferHub (https://transfer.nako.de/transfer/index).

The Tumor Tissue Bank of the German National Cohort (NAKO): Pilot of a Centralized Epidemiologically Networked Biobanking

by Katharina Hofmann | Nicole Großkinsky | Alexander Brobeil | Peter Schirmacher | Institute of Pathology, Heidelberg University Hospital, Germany | NAKO e.V., Heidelberg, Germany | Institute of
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Topic: 8A: The Transformative Role of Biobanks in Public Health
Presenter Name: Katharina Hofmann
Keywords: Biobanking, Cancer, Epidemiology, German National Cohort, NAKO

The NAKO Health Study (German National Cohort) is a nationwide long-term populationbased study carried out since 2014 with 200,000 participants, recruited by 18 study centers. The aim of NAKO is to gain knowledge of how widespread diseases like cancer develop, to improve prevention, early detection, and treatment. The centralized

Tumor Tissue Bank (TGB) collects, characterizes, validates, and stores pseudonymized tissue samples from participants of NAKO that develop cancer for future research.

The TGB is affiliated to the Tissue Bank of the National Center for Tumor Diseases (NCT), embedded in the centralized BioMaterialBank Heidelberg (BMBH). Available formalin-fixed and paraffin-embedded (FFPE) samples from cancer patients are identified with a database shared between NAKO, epidemiological cancer registries, and TGB and requested from the primary diagnostic pathologies via NAKO study centers. For development of strategic workflows, a pilot project with samples from study participants from Saxony (n = 54) was successfully carried out in December 2022 in cooperation with the Leipzig Cancer Registry, the Saxony state cancer register, and NAKO, considering specific provisions and ethical and regulatory frameworks. The samples are handled and stored in a quality-assured manner and are available for research requests, supported by project advice and management provided by TGB.

The successfully implemented processes of TGB show the feasibility and potential of joining quality assured tissue biobanking and provision of highly dimensional epidemiologic studies. This allows comprehensive analyses to multiple issues due to the connection with structured epidemiologic data raised by NAKO, and adds a new dimension to tissue-based cancer research.

p53 protein expression, TP53 gene mutations, and in silico p53 activity as prognostic markers for ovarian cancer

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Topic: 8A: The Transformative Role of Biobanks in Public Health

Presenter Name: Estrid Høgdall

Keywords: TP53, danish cancerbiobank, ovarian cancer, p53, prognostic marker

Introduction: The frequency of alterations in the *TP53* gene varies amongst different cancers. Data suggest an overall 47,8% occurrence of *TP53* gene alterations in ovarian cancer (OC).

The study aimed to investigate the prognostic impact of p53 protein expression, *TP*53 gene mutations and, *in silico* prediction of p53 activity.

Material and methods: Blood and tissue samples from 161 OC cases from the Danish Pelvic Mass/GOVEC study were collected through the Danish CancerBiobank (Bio- and GenomeBank, Denmark). We used immunohistochemistry (IHC) and sequencing to measure p53 protein expression, detection of *TP53* mutation, and *in silico* prediction to estimate the activity level of p53, respectively.

Results: P53 protein expression was found to have no prognostic value (Overall survival (OS): p=0.11; Progression Free Survival (PFS): p=0.26).

Multivariate analyses showed that patients with *TP53* missense mutation or *TP53*

termination mutation had shorter OS and PFS (*TP*53 missense mutation: p=0.008 and *TP*53 termination mutation: p=0.04).

Thirty patients with negative p53 expression had *TP53* mutation in the tumour tissue, while in 11 patients with positive p53 expression, had non *TP53* mutation found in the tumour tissue.

In silico p53 activity was found to have no independent prognostic value.

Conclusion: p53 expression negative tissue may optimally be subject to *TP53* sequencing. *TP53* termination mutations may represent a subgroup of patients with significantly shorter survival.

From multi-omics to better health – Managing the biological data resource in the Norwegian Mother, Father and Child Cohort Study (MoBa)

by Even Birkeland | Johanna Lucia Thorbjørnsrud Nader | Elin Alsaker | Sille Marie Vangbæk | Maria Aamelfot | Ragnhild Brandlistuen | Ragnhild Valen | Department of Genetics and Bioinformatics, Norwegian Institute of Public Health | Department of Genetics and Bioinformatics, Norwegian Institute of Public Health | Department of Health Studies, Norwegian Institute of Public Health | Department of Health Studies, Norwegian Institute of Public Health | 3. Department for Biobanks, Norwegian Institute of Public Health | 4. Department of Child Health and Development, Norwegian Institute of Public Health | 1. Department of Genetics and Bioinformatics, Norwegian Institute of Public Health

Topic: 8A: The Transformative Role of Biobanks in Public Health

Presenter Name: Even Birkeland

Keywords: Biodata, digital biobanking, genetics, multi-omics

The Norwegian Mother, Father and Child Cohort Study (MoBa) is one of the world's largest pregnancy cohorts. Since recruitment began in 1999, hundreds of thousands of biological samples including blood, urine, saliva and teeth have been collected from MoBa participants and stored at the biobank at the Norwegian Institute of Public Health (NIPH). These samples were primarily collected during pregnancy and at birth, in addition to a number of follow-up collections during childhood and adolescence. Despite their high value and hitherto untapped potential these data have not been available for re-use to the wider scientific research community in line with the FAIR principles. Historic large scale sensitive data poses several challenges to ensure data quality, governance, and data privacy. To make data available we propose a stepwise process that incorporates legal and scientific assessment together with thorough documentation and standardization. The digital biological resource in MoBa now provides genetic, epigenomic, metabolomic, proteome and exposure data, made available for research. Combining data types across diverse omics categories linked to Norwegian health registries, allows for higher precision in identifying biological mechanisms associated with complex disease.

The biological data resource in MoBa now includes whole genome SNP-array on 235.000 participants, methylation array on 15.000 participants, metabolomics of 15.000 participants with steadily increasing overlap on data from each participant, all thanks to individual research projects. The nature of large-scale molecular data demands tailored infrastructures and management models to ensure data quality, increased availability, and ease of use.

Bridging Continents, Advancing Health: Qatar Biobank's Vision for a New Era in Precision Health

by Fatima M. Qafoud | Qatar Precision Health Institute, Qatar Foundation

Topic: 8A: The Transformative Role of Biobanks in Public Health
Presenter Name: Fatima M. Qafoud
Keywords: Qatar biobank

As the world transitions from traditional public health models to precision health, biobanks are playing a pivotal role in shaping the future of disease prevention, early detection, and personalized treatment. **Qatar Biobank (QBB)** is at the forefront of this transformation, serving as a bridge between continents by fostering international collaborations and advancing health through cutting-edge research and innovation.

With a diverse cohort of over **30,000 participants**, QBB is generating high-quality **multiomics, clinical, and lifestyle data**, contributing to **global precision medicine initiatives**. By integrating **artificial intelligence, big data analytics, and genomic research**, QBB is driving **personalized disease prevention strategies**, influencing **national health policies**, and strengthening global efforts to **close the gap in genomic diversity**.

This presentation will highlight **QBB's vision for the future**—where biobank-powered research accelerates **precision health**, ensuring **equitable and effective healthcare solutions worldwide**. It will explore opportunities for **collaboration between European, Middle Eastern, and global biobanking networks** to enhance **data sharing, AI-driven health predictions, and personalized public health strategies**. Through these efforts, **QBB aims to not only advance health outcomes within Qatar but also contribute to a new era of precision health on a global scale**.

10A: Organisational Profiles

Pan-African Biobanking Network (PABNet): Strengthening the African Biobanking Community

by Sandra Nanyonga | Daniel Simeon Dubach | Zisis Kozlakidis | Universite Cote d'Azur | Medservice | IARC

Topic: 10A: Organisational Profiles
Presenter Name: sandra Nanyonga
Keywords: African, Biobanking, Community,PABNet

Challenge
Establishing and managing a biobank in Africa requires compliance with multiple laws and regulations, which vary by country. Navigating these complexities can be challenging for biobankers across the continent.

Solution
Founded in 2024, PABNet serves as a central platform supporting African biobankers by providing critical resources and fostering collaboration.

Building a Stronger Biobanking Community
The diverse regulatory landscape in African countries underscores the need for greater connectivity and cooperation. To better understand this landscape, we conducted a survey amongst African biobankers to gather essential insights. Future surveys will help refine our understanding of their evolving needs.

PABNet's website offers a comprehensive repository of standards, laws, and regulations, categorized by country. Local experts ensure this information remains up to date, making it an invaluable resource for biobankers.

Our next priority is capacity building. By addressing the specific needs identified, we will develop targeted educational programs aligned with local regulations. Collaborations with key stakeholders will further enhance the impact of these initiatives.

Additionally, we aim to streamline and adapt quality management systems (QMS) for African biobanks, ensuring they are practical, accessible, and compliant with relevant standards.

Conclusion

PABNet is a community-driven initiative tailored to Africa's unique biobanking challenges. By fostering knowledge-sharing and capacity building, it will contribute to the growth of a sustainable, well-regulated biobanking ecosystem across the continent.

Bridging departments: A Standardized Form to Streamline Sample Management Across the Hospital

by Natascha Perales Selva | author

Topic: 10A: Organisational Profiles
Presenter Name: Natascha Perales Selva
Keywords: , interdepartmental, operational efficiency, sample flow, standardized form

Introduction

Efficient management of study-specific sample workflows from hospital departments to a biobank laboratory is essential but challenging due to unclear processes, poor communication, and incomplete documentation, all of which can negatively affect sample quality and research outcomes. To address these issues, a standardized form was developed in collaboration with biobank staff, researchers, and supporting departments. This form provides clear instructions, assigns responsibilities, and consolidates actions across pathology, clinical biology, and the biobank laboratory. It also assists the study design team in configuring studies within the laboratory information system (LIS) and enables accurate cost estimation for study-specific contracts.

Materials & Methods

The form was designed through a multidisciplinary effort to streamline sample workflows across the hospital. It specifies the responsibilities of each stakeholder, ensuring consistent registration, processing, storage, labelling, kit creation, safety considerations and shipment of samples. During the pilot phase, its usability and impact were tested, and feedback was collected to refine the process.

Results

The form has enhanced workflow clarity and coordination, allowing researchers to focus on patient-related tasks while laboratory staff handle technical processing. Even when departments process samples independently, a simplified version of the form enables the biobank to maintain an overview of study-specific sample flows. Key challenges remain, the form's complexity requires some expertise to complete. Development of a dynamic, webbased version is therefore necessary.

Discussion & Conclusion

The form has improved communication and sample quality. Future improvements, such as advance notification systems and clearer interdepartmental agreements, will further optimize workflows and foster collaboration.

canSERV – providing cutting edge cancer research services across Europe

by Judit Balogh | Manuela Pausan | John Eriksson | Serena Scollen | Vitor Martins dos Santos | Enzo Medico | Bahne Stechmann | Michael Hagn | Corinna Brockhaus | Stéphane Lejeune | Zisis Kozlakidis |

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UK | EORTC, Brussels, Belgium | IARC/WHO, Lyon, France | INFRAFRONTIER, Neuherberg, Germany |

EMBRC, Paris, France | ECRIN, Paris, France | Fundacio Privada Institut D'Investigacio Oncologica De

Vallhebron representing Cancer Core Europe, Barcelona, Spain | EATRIS, Amsterdam, Netherlands |

Universidade do Minho representing MIRRI, Braga, Portugal | ttopstart, Rijswijk, The Netherlands |

University of Manchester representing ARIE, Manchester, UK | BBMRI-ERIC, Graz, Austria

Topic: 10A: Organisational Profiles

Presenter Name: Manuela Pausan

Keywords: cancer research, precision medicine, research infrastructures

Background: canSERV is a € 15 Mio. project offering cutting-edge research services, enabling innovative R&D projects and fostering precision medicine for patients benefit. canSERV involves 18 leading organizations across Europe including Research Infrastructures, key organisations and oncology experts.

Objectives: canSERV's main objectives are: (i) offer at least 200 different unique Personalised Oncology relevant and valuable cutting-edge services; (ii) establish a single, unified, transnational access platform to request services and trainings; (iii) ensure oncology-related data provided will be fully compliant with FAIR principles and complement and synergise with other EU initiatives and (iv) ensure long-term sustainability beyond project duration. Furthermore, canSERV establishes the European Molecular Tumour Board Network (EMTBN) that is open for anyone to join. The EMTBN develops Molecular Tumour Board (MTB) consensus guidelines, an MTB outcome registry, and provides advice to scientists, clinicians, and MTBs.

Results: canSERV offers a series of open and challenge calls for access to services in the amount of ~ € 9 Mio. The calls are designed to support researchers to develop innovative research projects that explore cutting-edge methodologies and target critical gaps in cancer research and care by providing funding to resources/services. By encouraging the submission of collaborative proposals, canSERV aims to foster transnational cooperation, support a vibrant scientific community, and help to accelerate knowledge gain and transfer through defragmenting the European Research Area.

Conclusions: canSERV presents an unparalleled opportunity to accelerate cancer research, drive innovation, and improve patient outcomes. canSERV is granted by the EU Horizon programme under #101058620.

The importance of a functioning Disaster Recovery Plan: the successful experience of IRCCS Istituto Romagnolo per lo Studio dei Tumori (IRST) "Dino Amadori", Meldola, Italy during the 2023 flood

by Valentina Ancarani | Monica Forni | Margherita carpani | Massimiliano Petrini | Luca Battistelli | Laura Ridolfi | Biobank Unit, IRCCS Istituto Romagnolo per lo Studio dei Tumori (IRST) "Dino Amadori",

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Topic: 10A: Organisational Profiles

Presenter Name: Valentina Ancarani

Keywords: Disaster Recovery Plan, Organizational aspects

"Anything that can go wrong will go wrong." Several cases of misfunction, human mistake and natural disaster (University of Rochester NY- USA, Karolinska Institutet StocholmSweden) have generated the loss of incalculable value of samples and resources. On 16th and 17 th May 2023 Romagna area suffered dramatic flooding caused by the effect of climate change in an area at high hydrogeological risk. Despite the immense damage to the infrastructures and the state of emergency that lasted for days, the institute, thanks to a well-studied disaster recovery plan (DRP) and the timely and coordinated intervention of the executives, managers, front liners and service providers, succeeded in saving all biological samples in the biobank's assets.

We recorded and analysed the steps and factors that grant the success of the DRP, following the tailoring of the plan according to the structure, the strategy adopted in choosing the service provider.

Strategic choices can be made “by design” since the construction of the biobank considering the growing chance of the happening of disruptive episodes. The implementation of procedures and practices according to ISO 20387:2020 standards and the careful, updated and repeated training of all the personnel are key factors for the success and reliability of a DRP.

Positive and negative experiences have to be compared and discussed to reduce the risk of damage or loss of samples stored into the biobanks. It will also be increasingly important for the future to consider the DRP as a valuable insurance instead of a burden for the economic cost.

TRACK 2. Bridging the Gap: Biobanks and Data-Driven Research

3B: Biobanks in Big Data Research and AI

Biobanks as strategic tools in the concept of national digital medicine centres network establishment in Poland

by Agnieszka Matera-Witkiewicz | Magdalena Krupińska | Wiktoria Syska | Agnieszka Jakuszak | Przemysław Wieczorek | Joanna Gleńska-Olender | Screening of Biological Activity Assays and Collection of Biological Material Laboratory, Wroclaw Medical University Biobank, Wroclaw Medical University, Wroclaw, Poland | Screening of

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Topic: 3B: Biobanks in Big Data Research and AI
Presenter Name: Agnieszka Matera-Witkiewicz
Keywords: Big Data Sets, Biobanks, Medical data, digital medicine, digitalization, network

Introduction: Polish Government Plan for Development of Biomedical Sector 2022-2031 perspective presented by Medical Research Agency, national ECRIN infrasturcture member, has assumed the formation of 19 Regional Digital Medicine Centres (RDMCs).

Materials and Methods: RDMCs as organisational units responsible for processes associated with the implementation of innovative digitisation instruments, are dedicated for development and effective useage of medical records and Big Data sets based on universities, hospitals and biobanks collected resources.

Results: The main goal is an implementation of unified standard for collection and processing of high quality medical data for research purposes, ensuring safe sharing of structured information in national and international collaboration. Biobanks, being the core of the RDMCs, are responsible for international ISO standards and national Quality Standards for Polish Biobanks implementation and maintenance.

Conclusions: RDMCs based on biobanking facilities will independently develop tools and techniques for working with data. The idea is to create and implement smart solutions, including AI/ML tools for prognostic, predictive and therapeutic algorithms based on clinical and omic data sets. Also, data integration and analysis as a part of Picture Archiving and Communication Systems (PACS) and Vendor Neutral Archives (VNAs) dedicated to medical images from different sources will fulfill the system. Finally, the national concept of RDMC's formation strictly cover the 10-year BBMRI-ERIC RoadMap Strategic Objective 2 (Accelerate datafication to enable trustworthy, fit for-purpose data for high-quality research) dedicated for ensuring international interoperable connectivity with local, national and international medical data ecosystems.

Acknowledgement: This work is supported by Medical Research Agency Grant ABM.D250.24.001.

Federated research infrastructure: Interoperable trusted research environments for researchers by biobanks

by Pauli Wihuri | FINBB

Topic: 3B: Biobanks in Big Data Research and AI
Presenter Name: Pauli Wihuri
Keywords: federated, infrastructure, research, trusted

Introduction

Researcher's access to biobank data takes typically weeks or even months! Biobanks as data sources need to build services, which enable researchers *Next Day Access to Data*.

Data sources need to control access to the data and obtain trust that researchers handle the data according to the agreed research protocol. On the other hand, researchers are familiar with own research tools, solutions and environments. Furthermore, many researchers are not technologically savvy and require seamless research tools.

Would it be possible to build connected and interoperable trusted research environments where both data source and researcher needs are met?

Materials & Methods

Life science organizations have built own data and research environments for their own use within their collaboration ecosystem with own research tools and solutions by using a selected public or private cloud infrastructure and cloud services (or on-premises).

Typically, environments are not connected nor interoperable with each other enabling crossorganizational research collaboration.

Furthermore, investments into separate trusted data management and research environments are enormous within EU alone.

Results & Findings

We discuss concepts and solutions enabling connected and interoperable trusted data management and research environments providing online collaboration between data sources and research programs while also fulfilling both parties' needs.

Discussion & Conclusions

The architectural model for online collaboration between data sources and research institutions enabling researchers next day access to biobank data and biobanks data controls with mutual trust.

Emerging challenges of Biobank Network Japan: transformation biobank through AI technologies

by Soichi Ogishima | Koichi Matsuda | Yuji Goto | Biobank Network Japan research group | Toshihisa Takagi | ToMMo, Tohoku Univ | IMS, Tokyo Univ | Natl Ctr for Global Hlth and Med and Natl Ctr for Neur Psych | Biobank Network Japan | Toyama Intl Univ

Topic: 3B: Biobanks in Big Data Research and AI
Presenter Name: Soichi Ogishima
Keywords: AI, biobank network, large-language model

In Japan, to facilitate research of genomic medicine, we established a network of major biobanks in Japan and developed a system for utilizing biospecimens and data. We have provided a biobank cross search system on over 1 million biospecimens and data in our biobank network and a web-based coordination system of fast access to them to meet the requests by academic/commercial users. Our biobank network promotes various researches of genomic medicine. Nevertheless, there are still issues. First of all, for researchers, there are still difficulties in understanding the complex processes involved in accessing biospecimens/data and ensuring that they proceed smoothly. Moreover, the data stored in biobank are becoming huge and more complex, and it is becoming more difficult for researchers to understand and utilize it efficiently. Biobanks store not only biospecimens and associated data but also complex datasets including genomic data, longitudinal clinical, omics, and

epidemiological data. To fully utilize the extensive biospecimen and data, researchers must deepen their understanding of huge and complex data in biobanks. In recent years, generative AI has been progressing rapidly. Large-scale language models enable an intuitive and efficient interface to bridge this complexity. LLMs also enable sophisticated natural language searches across diverse datasets, addressing the complexity of biobank queries. This capability not only accelerates research but also democratizes access to biobank resources, making them more accessible to a wider range of users, including those with limited technical expertise. In Japan, efforts are ongoing to integrate generative AI into biobanking, enhancing its efficiency and applications.

4B: Navigating the Technical Hurdles of the Upcoming European Data Spaces

Data transfer agreement in the era of EHDS and AI

by Dorota Krekora-Zając | Faculty of Law and Administration University of Warsaw, ELSI Grup BBMRI.ERIC

Topic: 4B: Navigating the Technical Hurdles of the Upcoming European Data Spaces
Presenter Name: Dorota Krekora-Zając
Keywords: DTA, EHDS, biobank, legal responsibility

Introduction:

EHDS is the new opportunity for biobanking and training AI tools. Very broad possibility of secondary use of data in EHDS and using data in Data Space make a new challenges for data transfer agreement between biobanks and researchers.

Material & methods:

The subject of the study was the contractual templates used by biobanks in Poland and selected EU countries and the analysis of obligations and rights for biobanks resulting from
EHDS.

Results:

The entry into force of EHDS will cause revolutionary changes in the scope of obligations and rights of biobanks and will require the creation of new data transfer agreement templates.

Discussion and conclusion:

EHDS requires starting a discussion on legal responsibility of biobanks and researcher and the data subject rights. The question arises to what extent biobanks will be able to independently determine the rules for data transfer based on EHDS. Biobanks will have to create new rules for access to their own data sets.

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Genomic Data Transfer via Secret Sharing Based Storage Network in the BBMRI.it Infrastructure

by Davide Fragnito | Alice Massacci | Christoph Pacher | Philipp Stanzer | Okan Ecevit | Werner Strasser |

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Topic: 4B: Navigating the Technical Hurdles of the Upcoming European Data Spaces
Presenter Name: Davide Fragnito | Alice Massacci
Keywords: BBMRI.it biobanks, Genomic data, data transfer, fragmentiX®, secret sharing, storage optimization

Motivation

In the context of the European Data Spaces (e.g. EHDS and EOSC), biobanks, hospitals, and biorepositories face significant challenges in data transfer and storage. This is particularly critical for hypersensitive or non-fully (pseudo) anonymizable data, such as genomic data, which contains a unique fingerprint of the profiled individual [1]. The main challenge is to balance efficient handling of large data flows [2] while ensuring resilience against increasing cyber threats like encrypted or ransomware attacks.

Methods

A pilot test was conducted on public FASTQ files from the European Nucleotide Archive (projects: PRJEB5863, PRJEB5753, PRJNA302837) [3]. Files were selected to facilitate storage and flexible dataset partitioning. Transfer technologies included Windows (fragmentiX® Storage Solutions client) and Ubuntu (rsync/scp commands). The fragmentiX® appliance makes use of secret sharing to create a cryptographically secured distributed data repository in the cloud and on premises. The main test center is part of the CNR-IEOMI (Naples) cluster, funded by the «Strengthening BBMRI.it» project [4]. Future tests will include additional nodes, such as UNIMIB (Milan), headquarters of the national BBMRI.it node.

Results

Transfer speeds on a 1GB bandwidth varied from 1Mbps to 126MBps for file sizes between 100KB and 10GB. Several optimization processes are in progress to enhance read/write speeds and overall data handling efficiency.

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5B: Ensuring Data Security in Biobanks: Strategies and Best Practices

Current data security issues in biobanking

By Dr. Georg Göbel
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Topic: 5B: Ensuring Data Security in Biobanks: Strategies and Best Practices
Presenter Name: Dr. Georg Göbel
Keywords: data security

7B: Data Flows in Healthcare Integrated Biobanking

Information System Architecture of the Lithuanian National Biobanking Infrastructure

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Topic: 7B: Data Flows in Healthcare Integrated Biobanking
Presenter Name: Mindaugas Morkunas
Keywords: Data integration, National infratsructure

Introduction
In 2019, six Lithuanian institutions launched the Human Biological Resource Center (HBRC) project to create a modern national biobanking infrastructure and join BBMRI–ERIC. Partners signed a Joint Activity Agreement to establish a unified system for managing biological samples and health information, delegating Vilnius University Hospital Santaros Klinikos (VUHSK) as the lead IT implementer.

Rapid biobanking development in Lithuania, driven by the need for high-quality samples and datasets, resulted in inconsistent procedures, fragmented collections, and delayed accessibility.

Methods
We designed and implemented a comprehensive biobanking information system for HBRC, integrating hospital infrastructure (HIS of three hospitals), biobank laboratories and storage (MBioLIMS), and IT infrastructure for networking (participant registry, HIS, and State Data Agency integrations), thus effectively addressing operational obstacles.

Results
We present a VUHSK Biobank case study with 12,300 participants enrolled by June 2024. Participants contributed to 35 collections (averaging 750 participants and 3100 samples per collection). Nearly 200,000 samples of 24 types are stored, most frequently Blood, Serum, PBMC, and RNA. The enrolled participant's clinical database contains over 101,500 inpatient, 823,200 outpatient, 6,200 emergency encounters, and 120,000 DICOM images (US, CR, CT) representing diverse disease categories - cancers and blood disorders (D70D77 - 33.2%, C81-C96 - 32.2%, D60-D64 - 29.1%), infections (U00-U49 - 29.2%, A30-A49 18.9%, B95-B97 - 8.2%), other conditions (E70-E89 - 38.2%, I10-I15 - 35.0%, J09-J18 -
24.7%).

Discussion & conclusion
VUHSK Biobank feasibility study demonstrates the value of integrated biobanking information management, which effectively leverages clinical information, images, and biosamples to foster future collaborations.

Integration of the Biobank Information Management System (BIMS) with the Electronic Health Record (EHR)

by Santiuste, I | Martínez-Magunacelaya, N | De la Fuente, A | Canale, L | Arozamena, J | Madureira, R | García-Gallego, M | Batlle-López, M.A | Saez, R | Marin-Vidalled, MJ | Biobanco Valdecilla- Instituto de

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Topic: 7B: Data Flows in Healthcare Integrated Biobanking

Presenter Name: Santiuste, I

Keywords: Biobank, Clinical Data, Health Record, IMS, Integration, Sample

Introduction:

Biobanks play a key role in bridging clinical research and healthcare by managing extensive biological sample collections with associated clinical data while ensuring compliance with ethical and legal standards. Hospital biobanks primarily rely on samples and data obtained from routine healthcare activities. Therefore, integrating biobanks into hospital systems as a standard service is essential. This project aimed to integrate the Valdecilla Biobank Information Management System (BIMS) with the Electronic Health Record (EHR) and the laboratory Information Management System (LIMS) of Valdecilla hospital.

Material and Methods:

The integration required collaboration with IT developers and the hospital IT department. A "*biobank request*" was added to the request system to structure clinical data entry, specify required samples, and confirm donor consent.

When a biobank request is submitted, an HL7-OML_021 message is generated, containing demographic and request details. This message is sent simultaneously to:

1. The LIMS, ensuring samples follow the same process as clinical samples.
2. The BIMS, where donor data and samples are automatically recorded.

Additionally, the IT department updates donor demographic information in the BIMS.

Results and Conclusions:

The integration is fully operational across all hospital departments recruiting research patients. In the first twelve months, more than 90% of biobank requests were processed through this system. This development enhances efficiency, reliability, and traceability in request management and clinical data transfer, contributing to high-quality research and improved healthcare practices.

An Extract, Transform, Load foundation for Biobank Data Interoperability

by Antonella Cruoglio | Federica Rossi | Davide Fragnito | Ramona Palombo | Alice Massacci | Martina Betti | Mattia D'Antonio | Massimiliano Borsani | Claudia Miele | Gennaro Ciliberto | Marialuisa Lavitrano

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Topic: 7B: Data Flows in Healthcare Integrated Biobanking

Presenter Name: Antonella Cruoglio | Matteo Pallocca

Keywords: FAIR; Common Data Models; Federated Search; Biobanking; Health Information Interoperability; Clinical Informatics; Clinical Bioinformatics.

Motivation: Federated Search is essential for Research Infrastructures like Biobanks, enabling rapid identification of Biobanked Samples based on desired features, particularly crucial for investigating rare phenotypes. The main prerequisites are the conversion of a local database into a Common Data Model (CDM), and the setup of an internal server node in which the CDM database is loaded and made accessible for external queries. The first one is usually challenging for Biobanks lacking sufficient technical support to improve data FAIRness. This is achieved through a local Extraction, Transformation, and Loading (ETL) process, typically using data from a Biobank Information Management System (BIMS).

Methods: We present *a-small-fire* (https://github.com/bbdataeng/a-small-fire), a framework for converting minimal dataset based on MIABIS (https://github.com/BBMRI-ERIC/miabis) into HL7-FHIR transaction bundles, enhancing basic Biobank Interoperability and facilitating connection to the BBMRI-ERIC European Federated Platform. The toolkit includes Python modules that generate JSON files for upload to a local FHIR server connected to the federated network, enabling data sharing and query execution.

Results: *A-small-fire* improves data harmonization and standardization by integrating with local information systems, promoting data sharing, enhancing data quality, and advancing research and reproducibility. Tested on three Italian biobanks (Rome, Naples) specialized in oncology and pediatric rare diseases, this tool, developed within the #NextGenerationEU "Strengthening BBMRI.it" project, is available as a preprint (https://zenodo.org/records/14012269) and will be submitted to a Computer Science journal focusing on Information Systems and Data Quality.

Electronic Order Entry and Biobank Registration for Tissue Samples

by Michael Neumann | Alexander Birkenkamp | Hansgeorg Molnar | Matthias Rambow | Roland

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Topic: 7B: Data Flows in Healthcare Integrated Biobanking
Presenter Name: Michael Neumann
Keywords: Healthcare Integrated Biobanking, Tissue Samples, Workflow

Introduction: One of the key challenges in healthcare-integrated biobanking is seamlessly incorporating the sample collection process into the daily clinical routine. For add-on liquid biosamples, the sample information is created in an Electronic Order Entry System (EOES) and is automatically transferred to the Biobank Information Management System (BIMS). For tissue samples, the process is often paper-based and involves several manual steps, which heighten the risk of errors and reduce the overall efficiency of the process.

Material and Methods: We have enhanced the existing EOES to not only facilitate the creation of add-on liquid biobank samples but also to request leftover tissues from routine histopathology. The key difference between the two sample collection methods is that liquid sample collection is entirely independent of the corresponding diagnostic process, while tissue samples are only collected from leftover material if the pathologist in charge grants approval. In this case, the pathologist is notified of the request for leftover material via the Pathology Information System. Once the pathologist decides to submit some of the leftover tissue samples to the biobank, the corresponding case is automatically transferred to the BIMS.

Results: Complete digitization of the tissue sample requesting and registration process provides an efficient and reliable way of collecting tissue samples in a clinical setting. Integrating the initial request into the EOES also helps to prevent the generation of the request if there is no valid consent available for the patient in question.

8B: Best Practices for Biobanking Data Integration

Health-RI, the federated Dutch national research infrastructure for data-driven health and life sciences

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Topic: 8B: Best Practices for Biobanking Data Integration
Presenter Name: Janet Vos
Keywords: EHDS, EOSC, ESFRIs, Research infrastructures, health and life sciences, national infrastructure

The Netherlands has been a member of BBMRI since its foundation. Since 2023, BBMRI.nl is hosted by Health-RI, the national health & life sciences data infrastructure. Health-RI is set up to enable data-driven health & life sciences research in the Netherlands and to provide the

infrastructure to make health and life science data reusable at scale for research, policy making, and innovation. Health-RI organizes this infrastructure and implements the Dutch Open Science and FAIR data policy by making knowledge, equipment, and research data optimally accessible.

Health-RI assembles an ecosystem of complementary federated national hub-node structures, where Health-RI is the hub and nodes are formed by region, domain (e.g. cancer), and ESFRI participation (EATRIS, ELIXIR, BBMRI), and in which we collaborate with university medical centers, universities, private research organizations, patient organizations, national ministries, and funders.

Health-RI focusses on connecting national and European initiatives related to data, biomaterials, and images, specifically when these concern health and life sciences, and actively participate in activities related to European infrastructures and data spaces (e.g., GDI, CANDLE, EUCAIM, EOSC4Cancer, EOSC-ENTRUST, EATRIS-CONNECT, ELIXIRSTEERS, EvolveBBMRI, HDAB-NL, TDCC-LSH). We bundle capacities of the Dutch research field and work towards a shared international-grade service portfolio for data-driven health&life sciences. This includes the national ELSI helpdesk and aims to connect infrastructural solutions from individual research infrastructures.

The current organization facilitates increased alignment and collaboration between individual research in Semmelweis Federated Platform: privacy-preserving integration of biobank and genomic data

by Viktor Molnár | Ákos Tényi | Marcell Zoltay | Zsolt Bagyura | Barbara Molnár-Érsek | Csaba Bödör | Peter Antal | Mária Judit Molnár | Institute of Genomic Medicine and Rare Disorders, Semmelweis

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Topic: 8B: Best Practices for Biobanking Data Integration

Presenter Name: Viktor Molnár

Keywords: MIABIS, Privacy-preserving Federated Learning, family history, gVCF catalog

The Semmelweis Biobank Network gathers a diverse range of biological samples and clinical data from multiple sources, including routine clinical operations and scientific research projects. However, these data repositories are fragmented, managed by diverse and non-interoperable documentation systems, limiting their broader utility. Biobanks are well-suited

for developing secure methods to share sensitive health and genetic data.

Our project seeks to build a flexible ecosystem that connects research and diagnostic datasets using Privacy-Preserving Federated Learning. By harmonizing biobanked data, it enables secure generation of summary statistics across available datasets

The data harmonization strategy ensures interoperability by adhering to BBMRI standards, including the MIABIS data model, and by using standardized phenotype and disease ontologies for both rare and common conditions. Clinical data integration is further supported by a software tool for prospective dataset augmentation. Mapping existing datasets has identified synergies and overlaps, helping to unify collection efforts and enhance analytical potential. Notably, incorporating family history data could improve genetic risk assessments and association studies, further strengthening research outcomes.

Federated analysis functionalities focus on (1) characterizing the genetic landscape of the Hungarian population via a gVCF catalog, (2) conducting association studies, and (3) introducing a new function to estimate the number of available cases with specific genetic variants.

The development of an interoperable data warehouse with federated AI-driven data sharing—built on the FedX Federated AI platform of E-Group—serves as a pilot initiative. These advancements can help BBMRI Hungarian Node members implement data harmonization and secure data sharing within their institutions.

The project was funded under TKP2021-NVA-15.frastructures and provides opportunities and added value for the Dutch research community.

A digital, standards-based ELSI metadata approach to consent in Italian biobanking

by Sara Casati | Anthony J Brookes | Marialuisa Lavitrano | Sabato Mellone | Maria del Carmen Sanchez Gonzalez | Francesca Frexia | Spencer Gibson | Matteo Pallocca | Antonella Mirabile | Vittorio Melloni |

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Topic: 8B: Best Practices for Biobanking Data Integration

Presenter Name: Sara Casati | Francesca Frexia

Keywords: BBMRI.IT, Citizen Biobanking, DUC/CCE, ELSI metadata integration, digital consent

The BBMRI.it community faces challenges of engagement, sustainability, and practical integration to establish digital, standards-based ELSI metadata regarding consent and use conditions. The concept of next-generation biobanking marks an evolution of research infrastructure towards federated solutions, undertaken as part of the Strengthening BBMRI

project, funded by the EU Next Generation Initiative.

Real-world implementation requires a paradigm shift that includes biobank participants as proactive partners. This entails dynamically integrating their informed consent—represented as CCEs (Common Conditions of use Elements)—within the biobanking and biomedical research IT ecosystem. Doing so will facilitate biobank tracking and ensure ethical, fair, and sustainable consent for biobanking and research purposes. This must be participatory, transparent, and integrated into the biobank governance and research infrastructure.

To this end, we are undertaking an Italian pilot project to characterize biobank samples using ELSI metadata in an interoperable format to facilitate interaction between biobanks, participants and third parties. The approach involves an App that will provide a two-way digital interface between participant-citizens and biobanks, created with the BBMRI community (including clinicians, DPOs, and representatives of patients, citizens, and mature minors). Its matrix structure will offer pseudonymized consent options based on CCEs plus a consent data model under construction (in HL7-FHIR format), inspired by the DUC/CCE framework validated during the European Joint Programme on Rare Diseases. Prototyping will focus on setting up consent metadata with a profile ready to be integrated into the BIMS software, which already powers a federated discovery network.

The case of and for longitudinal cohort studies

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Topic: 8B: Best Practices for Biobanking Data Integration

Presenter Name: Mandy Vogel

Keywords: cohort, data mangement, pediatric longitudinal samples

Introduction

Integrating and managing data in a longitudinal, ongoing cohort study involving different institutions across a multitude of

disciplines presents many challenges. Changing methods, evolving standards, new data types and formats must be integrated and harmonized to ensure long-term accessibility and usability of samples and data.

Material
The LIFE Child study [1,2], which began in 2011 and is still active today, has amassed over 700,000 biological specimens from nearly 6,000 children and their parents, spanning from prenatal development to early adulthood. Data (incl. medical history, psychological tests and questionnaires, laboratory, OMICS, etc.) and samples (incl. blood, urine, hair, teeth, etc.) from more than 26,000 visits are available for researchers worldwide. To ensure optimal and worthwhile use of this scientific treasure chest, close collaboration is essential between the study center, biobank, data management, and the responsible scientists.

Results
Over the past 15 years, we have built a robust and effective infrastructure to serve as a solid foundation for numerous research initiatives in collaboration with both commercial and nonprofit research entities. Within the LIFE Research Center for Civilization diseases, including our partner study LIFE Adult [3], over 800 project proposals were approved, many involving the provision of biosamples to international partners. Samples are provided and data is shared according to current legal and ethical standards, which are updated regularly. Any derived data is returned to the research database, making it available for future studies.

Conclusion
Prospective, longitudinal cohort studies provide ample research opportunities and provide the means to answer numerous research questions.

9B: Pitch your innovative idea

Imagene: Breakthrough in Biospecimen Preservation with a Sustainable Cold Chain-Free Solution

by Magali Milhau | Marthe Colotte | Imagene, France | Imagene, France

Topic: 9E: Pitch your Innovative Idea
Presenter Name: Magali Milhau
Keywords: Biospecimens room temperature preservation, Cold chain-free technology, DNAshell® / RNAshell®, Eco-friendly solutions, Hermetic encapsulation, Long-term preservation, Sample security, Sustainable logistics

Imagene introduces an innovative solution for long-term biospecimen preservation at room temperature, eliminating the need for costly, energy-intensive and risky cold chain logistics.

This technology ensures unparalleled sample integrity for several decades, with over 15 years of real-time stability data on biospecimens, offering a reliable and sustainable alternative to conventional freezing methods. Samples are stored in fully hermetic DNAshell® / RNAshell® capsules under anoxic and anhydrous conditions, protecting them from contaminants, oxygen, and humidity fluctuations. Imagene's technology guarantees the highest standards of biosample security and integrity, redefining the future of biological preservation, and is particularly adapted for precious samples in clinical laboratories and biobanks.

Beyond its scientific and technical advantages, Imagene's approach is both cost-effective and

environmentally responsible. By eliminating ultra-low temperature storage, it significantly reduces operational costs and carbon footprint, making it a game-changer for biobanks, research institutions, forensic laboratories, and pharmaceutical industries. The elimination of refrigeration and freezing requirements enhances accessibility, especially in regions with limited infrastructure, facilitating global sample storage and transport.

To meet diverse needs, Imagene offers on-demand encapsulation services, allowing laboratories to benefit from its technology without investing in equipment. For highthroughput applications, such as shared use among multiple laboratories, Imagene provides encapsulation stations, enabling full in-house autonomy for sample storage.

With its proven long-term stability, unmatched sample protection, and commitment to sustainability, Imagene is redefining biospecimen storage. This innovation paves the way for a more efficient, scalable, and eco-friendly future in biobanking, life sciences, diagnostics and DNA data storage.

Empowering Research Institutions and Open Science with the Biological Resources Management Plan (BRMP)

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Topic: 9E: Pitch your Innovative Idea
Presenter Name: Mistou M-Y | Tixier-Boichard M.
Keywords: guidelines, management plan, open science

Introduction-The Biological Resources Management Plan (BRMP) is a concept designed to address the global challenge of managing and preserving biological resources (BR) obtained through scientific research. It focuses on inventorying, tracing, and optimizing the conservation of BR, enhancing their visibility, promoting sharing, and fostering global scientific collaboration. Unlike Data Management Plans, the BRMP specifically tackles the materiality of biological resources, offering a comprehensive approach for their sustainable management.

Methods. INRAe and the National Research infrastructure RARe decided to develop a standard BRMP, with the help of a steering committee (SC) and a technical committee (TC). SC is mapping existing recommendations and frameworks (ex: Codex 2004), known by biobanks and applicable to the many samples still hidden in laboratories. The TC is mapping existing courses or standards dealing with samples management. Biobank managers from different domains (micro-organisms, animals, plants, environment) are part of these committees together with open science experts.

Results-Two major challenges have been identified so far: the resistance to sharing samples in scientific communities (sense of property) and the concern of unnecessary administrative burden, which sometimes occur with the requirement of Data Management Plan to get funds. A strategy to meet the demand of researchers and to value biological resources is needed to overcome these obstacles.

Discussion- Biobanks should take the lead to develop and implement a BRMP for research laboratories. It will aid in planning research

projects by anticipating conservation and visibility needs for new collections. Collaboration within Europe would be beneficial, to proceed towards an open-samples policy.

Applications of post-mortem biospecimens in biomedical research on pediatric rare diseases

by Mariona Arañó | Hospital Sant Joan de Déu, Barcelona

Topic: 9E: Pitch your Innovative Idea
Presenter Name: Mariona Arañó
Keywords: autopsy, cell culture, fibroblast, pediatric, post-mortem, rare disease, skin biopsy

Introduction

Post-mortem human biospecimen collection provides a source of valuable samples, particularly relevant in rare pediatric diseases where sample availability is limited. Viable cells can still be found in these tissues, making them suitable for diagnostic and research purposes.

Material and Methods

Fibroblasts were obtained from either fresh biopsies (A) or autopsy-derived frozen biopsies without cryopreservants, which do not follow the gold standard for optimal cell preservation (B). 2D fibroblasts were obtained and cultured using standard protocols, and seeded on coverslips for immunohistochemistry (IHC) and immunofluorescence (IF) staining. 3D spheroids were generated using the hanging-drop method and cryosectioned at 6um for IHC and IF. Markers for proliferation, apoptosis, senescence and functionality were assessed.

Results

We successfully obtained and characterized 2D and 3D cultured fibroblasts from conditions A and B. Fibroblasts from condition B exhibited similar proliferation and apoptosis rates, increased number of senescent cells, and partially reduced functionality compared to those from condition A.

Discussion and conclusion

Post-mortem skin samples frozen without following the gold standard protocols can still be used to obtain viable fibroblasts, which show similar characteristics to those obtained under optimal conditions. This expands the potential use of samples frozen under outdated protocols.

Given the limited availability of biospecimens in the field of rare pediatric disorders, using these samples could enhance our understanding of these diseases, enable post-mortem diagnosis, and facilitate drug testing; overall offering a practical and valuable approach for translational research.

References *(please see separate pdf)*

Advancing AI-Powered Sample Management: Automating Sample Registration Through Imaging and Data Extraction

by Markus Albertini | Azenta Life Sciences, Massachusetts, USA

Topic: 9E: Pitch your Innovative Idea
Presenter Name: Markus Albertini
Keywords: CTMS integration, Clinical trials, artificial intelligence, barcode scanning, biobank automation, cloud computing, data integrity, data reconciliation, handwritten text extraction, imaging technology, lab workflow optimization, label recognition, operational efficiency, sample automation, semi-automated registration, tube labeling

Automating clinical trial sample management has been hindered by the diversity in tube types, labeling formats, and metadata requirements. Labels may contain printed and

handwritten elements, varying across trials, therapeutic areas, and sponsor specifications. This heterogeneity presents challenges for central labs and repositories tasked with cataloging data in standardized formats compatible with diverse sponsor CTMS systems. Furthermore, clinical and specialty labs may lack the tools to handle pre-barcoded labels without human-readable text, increasing complexity.

To address these issues, Azenta developed an AI-powered semi-automated system integrating advanced imaging technology and tube handling automation. The system captures high-resolution images of vials using high-density cameras while rotating the tube at high speed. Multiple images are stitched into a single, flattened label image, along with top and bottom views of the tube.

These images are uploaded to a cloud-based platform where sophisticated AI algorithms extract relevant data from barcodes, printed text, and handwritten annotations. Extracted data are reconciled against predefined sponsor-specific data structures and electronic manifests provided by clinical sites. Discrepancies are flagged for resolution, ensuring accuracy.

A pilot study involving 10,000 samples from 48 clinical trials showed an 85% success rate in accurate label data extraction. Future efforts aim to improve AI accuracy and scalability to accommodate a broader range of labeling scenarios. This system reduces human error, enhances data integrity, and streamlines workflows, setting a new standard for automated clinical sample registration.

10B: Ensuring Excellence: Elevating Data Quality in Biobanking

Common Provenance Framework and the ISO 23494 Provenance Information Model for Biological Material and Data

by Rudolf Wittner | Niina Eklund | Cecilia Mascia | Francesca Frexia | Markus Plass | Luca Pireddu | Simone Leo | Heimo Müller | Petr Holub | Jörg Geiger | BBMRI-ERIC & Masaryk University | BBMRI-ERIC

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Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking

Presenter Name: Rudolf Wittner

Keywords: provenance traceability reproducibility quality standardisation ISO biotechnology

Introduction

Reproducibility issues are prevalent in the life sciences. In response, the scientific community has called for improved provenance to document the entire research lifecycle, from biobank material acquisition to the translation of results into practice.

Materials and Methods

The development of the Common Provenance Framework (CPF) included partners from both academia and industry. The academic community was involved through open community meetings and several European projects, namely CORBEL, EOSC-Life, BY-COVID, EvolveBBMRI, and BIOINDUSTRY 4.0. Industrial partners collaborated through their involvement in these projects and their

membership in relevant ISO Technical Committees.

Results

We present the CPF and the ISO 23494 Provenance Information Model for Biological Material and Data series. The Framework provides an open conceptual foundation, serving as a horizontal basis for documenting and integrating provenance from heterogeneous sources. It addresses challenges such as provenance management, trustworthiness, and interoperability, enabling comprehensive documentation across research lifecycle, from sample acquisition and processing to data generation, integration, and analysis. An operational provenance infrastructure based on this framework is being developed within the EvolveBBMRI project to support BBMRI-ERIC's 10-year roadmap, where provenance is a key development priority. When adopted by biobanks, the framework can cover the entire spectrum, ranging from fundamental research to practical application, and product development by linking samples, with data and data analysis.

Conclusion

All adopters of the framework, including biobanks, can benefit from it by achieving traceability, enhanced quality assessment of samples/data, and reproducibility. The framework can also provide harmonised approach to demonstrate compliance with legal frameworks, such as European Data Spaces or EU AI Act.

Applicability of Project Management Tools in Reviewing ISO 20387 Compliance for Biobanking

by Judith Sabaté-del Río | Lim Wouchlim | Anna Sastre-Rodó | Gemma Aragonès | Noemi González-Abuín | Ada Soler-Ventura | Aina Rodríguez-Vilarrupla | Teresa Botta-Orfila | Biobank from Hospital Clínic

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Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking

Presenter Name: Teresa Botta Orfila

Keywords: Data management plan, ISO 20387 compliance, Project management tools, data quality

Introduction: This study examines the use of project management tools like the Data Management Plan (DMP) to ensure compliance with ISO 20387 standards for biobanking. It highlights secure, efficient, and cost-effective data management. The Business Model Canvas is also introduced to visualize and assess business models. Integrating knowledge from various disciplines improves the quality and reliability of biobanking processes.

Materials & Methods: We reviewed literature and case studies to identify key milestones, limitations, and solutions in biobank data and quality management. Indicators for data homogenization, annotation, migration, and cybersecurity were established. The DMP, created with Eina Cora, monitors these indicators, including sample quality control and incident management. Our LIMS system, NorayBanks, ensures DMP compliance. Python scripts automate procedures, reporting, and user categorization, enhancing dataset reproducibility and reliability. A new research computing platform centralizes data processing, storage, and analysis, enabling large-scale data integration and interdisciplinary collaboration.

Results: Integrating project management tools like the DMP and Business Model Canvas significantly enhances the ISO 20387 compliance review process. Key milestones and progress indicators provide a structured approach to biobank data management. New quality controls for samples are crucial for their critical review.

Discussion & Conclusion: The interdisciplinary approach, incorporating knowledge from various scientific and management disciplines, proves crucial in enhancing biobanking processes. Not all aspects depend solely on the biobank, requiring collaboration with IT, legal advisors, and other stakeholders to manage information. This study provides valuable insights and solutions for standardizing and securing biobank data management.

HORUS Biobank Project: An Innovative Way to Support University Hospital Biobanks in Their Journey to Enhancing Sample and Data Quality

by Ristorcelli E. | Centre Hospitalier Universitaire Vaudois (CHUV)

Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking Presenter Name: Ristorcelli E.

Keywords: CHUV, Data Quality, HORUS, Sample Quality

Introduction

In the rapidly evolving landscape within the regulated healthcare sector, efficient approaches to enable sample and data re-use are key success factors for research. Despite using Biobank Information Management Systems (BIMS), these solutions often prove too complex for researchers' needs. To address this, CHUV launched the HORUS Biobank project aiming to provide an intuitive solution to optimize biobank management in terms of interoperability and legal compliance. CHUV has expanded its BIMS portfolio with a solution

developed by the Swiss Biobanking Platform (SBP) on top of the DiData solution.

Material & Methods

In addition to the BIMS selection, the project evaluates current biobank management practices. The BIMS was interfaced with other institutional systems (i.e., consent management, clinical Datawarehouse) to streamline and optimize data capture. Pilots were conducted to verify that the solution was suitable for its intended purpose and use. Close follow-up was performed with biobank staff to ensure a smooth transition and adoption.

Results

The DiData solution enhanced by SBP modules significantly improved biobank sample management. Key benefits included enhanced traceability, reduced manual data entry, standardized data and regulatory compliance. The system also facilitated and improved researcher's access to biobank data in conjunction with appropriate registries.

Discussion and Conclusion

The successful implementation of the BIMS solution in CHUV portfolio demonstrates its potential to enhance biobank operations' quality and efficiency. By providing a robust and reproducible framework for managing biological samples, it supports CHUV biobanks in advancing biomedical research. Future work will focus on further deploying the BIMS solution and improving its associated support model.

FISMA for high quality and interoperable real-world data on Dystrophinopathies - FAIR from the start: From concept to reality

by Y.D. Krom | R.R. Snijder | R.J.A. Hoek | E.H. Niks | LUMC, Duchenne Center Netherlands | LUMC Biobank Organisation, Duchenne Center Netherlands | LUMC | LUMC, Duchenne Center Netherlands

Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking
Presenter Name: R.R. Snijder
Keywords: Duchenne Parents Project, Dystrophinopathy, FAIR, Netherlands, Registry, registration at the source

Real-world data is crucial to gain deeper insights and improve care for patients with neuromuscular diseases. FISMA (**F**ramework for **I**nformation **S**pecification, **M**odelling and **A**rchitecture) makes this data interoperable, exchangeable by adding context and enhances data quality at the source.

Duchenne Center Netherlands has developed and adopted a conceptual framework, FISMA, that allows capturing real-world data (RWD) as relevant, re-usable and semantically interoperable data. FISMA is drafted with expansion in mind: both within the field of dystrophinopathies (Duchenne and Becker muscular dystrophy), as beyond, to other neuromuscular diseases.

FISMA has a multi-faceted approach with several underlying principles:

- Data-elements embedded in their
- clinical context (real-world data)

Registered once (at the source) in a clinical setting (integration of research and healthcare)

- Unambiguously defined with
- internationally adopted ontologies,
- standards
- System-independent, allowing
- implementation in any data capture solution

Data is reusable for multiple purposes

Expandable without disrupting existing implementations.

Expandable to other neuromuscular diseases.

Being system-independent, FISMA can be implemented in locally available source systems to capture data. As we speak, the FISMA principles are used to create a multi-modal RWD capture solution at LUMC, and also at Radboudumc. A different poster, "*Gap analysis of 4year data in the Dutch Dystrophinopathy Database*", is a partial practical application of FISMA.

[*to the Scientific Committee: an article detailing FISMA is currently in preparation*]

Enhancing BIMS to Improve Registration Rates and Data Quality

by Nina Jansoone | Biobank Antwerp

Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking

Presenter Name: Nina Jansoone

Keywords: BIMS, dynamic reports and dashboards, real-time insights, user engagement

Introduction

Biobank Antwerp is an academic biobank. As according Belgian biobank legislation all samples and derivates thereof require registration in a biobank and given the limited resources of the biobank, the biobank is obliged to involve the researchers in the registration process. Biobank Information Management Systems (BIMS) are essential for managing biospecimen data. Researcher involvement results in challenges such as low registration rates and inconsistent data quality. An ongoing effort to customize our BIMS was initiated, focusing on optimizing workflows and improving user engagement.

Methods and results

BIMS usage patterns and internal audits were used to identify inefficiencies in registration workflows, data integrity and user compliance. This led to BIMS modifications such as automating repetitive tasks, enhancing error-checking mechanisms and introducing mandatory data fields. Additionally, dynamic reports and dashboards were developed to provide real-time insights into key metrics including registration trends and data quality indicators enabling more direct monitoring and follow-up by biobank staff.

Discussion & Conclusion

The incorporation of reports and dashboards led to the identification of a significant lack of registration and registration errors. This resulted in an iterative and user-interactive BIMS modification process. Ongoing adjustments continue to refine these outcomes. This initiative demonstrates how repeated enhancements can address barriers to BIMS adoption, foster broader user engagement, reduce operational overhead and contribute to the long-term success of biobank operations.

TRACK 3. Biobanks - Pathways to Quality and Efficiency

3C: Biobank Automation: Challenges, Opportunities and Solutions

Biobank Management Automation: Challenges, Opportunities, and Solutions

by Enrico Almici | Andrea Piovanelli | Adriano Fusco | Antares Vision Group | Antares Vision Group | Antares Vision Group

Topic: 3C: Biobank Automation: Challenges, Opportunities and Solutions
Presenter Name: Enrico Almici
Keywords: Automation, Biobank, Biological samples, Security, Traceability

Biobanks play a crucial role in storing and managing biological samples for research, clinical, and forensic applications. Despite existing software solutions, challenges persist in streamlining workflows, improving automation, and maintaining regulatory compliance. This work presents an automated approach to biobank management for National DNA Biobank of Minister of Justice Banca Dati Nazionale DNA (Dipartimento Amministrazione Penitenziaria – Ministero della Giustizia) using digital twin technology and GS1-compliant data carriers.

The project implemented an Biobank Management System (BMS) focused on dynamic asset management, digital identity tracking, and real-time monitoring of sample and storage statuses according to ISO standards. The system was developed based on the digital twin technology, assigning each sample and storage unit a unique identifier encoded in a GS1compliant data carrier. This identifier is linked to a digital twin stored in a web-based platform, to implement real-time monitoring of the sample's status, storage conditions, and handling history.

The system leverages the digital twin concept and GS1-compliant carriers for tracking biological samples, ensuring full traceability throughout their lifecycle. This enables realtime updates on sample location, status, and handling, reducing errors and ensuring regulatory compliance.

Findings highlight improved sample traceability, reduced human errors and enhanced data integrity. Real-time monitoring ensured visibility and control over stored material, optimizing sample retrieval and distribution. Future developments shall focus on integration of sensors and novel data carrier technologies. Real-time monitoring of transport and storage conditions along with automatic wireless code readers may streamline handling operations and minimize sample degradation risks, increasing long-term reliability and sample quality.

The Central Biorepository of the NAKO Health Study

by Andreas Hörlein | Julia Six-Merker | Matthias Nauck | Nina Wawro | Susanne Göttlicher | Thomas Hendel | Annette Peters | Helmholtz Munich | Helmholtz Munich | University Medicine of Greifswald | Helmholtz Munich | Helmholtz Munich | Helmholtz Munich | Helmholtz Munich, LMU Munich, Harvard School of Public Health

Topic: 3C: Biobank Automation: Challenges, Opportunities and Solutions
Presenter Name: Andreas Hörlein

Keywords: Automation, Biobanking, Kohort Study, Sample sorting

The NAKO Health Study is the largest cohort study ever performed in Germany. 205.000 participants have been examined in the baseline examination (2014-2019), 137.000 in the first follow-up examination (2019-2024) and 85.000 participants are planned for the second follow-up examination (2024-2028). A unique Central Biorepository was built and developed into its current operational state especially dedicated to the NAKO biosamples. It is equipped with two storage systems, a fully automated -180°C storage system and a semiautomatic -80°C storage system. Both storage systems were prototypes that were built by the company Liconic AG (Mauren, Liechtenstein). Currently, a total of 18.9 Mio. aliquots are stored in the central biorepository, of which more than 16.6 Mio aliquots are stored in the -180°C unit and more than 2.3 Mio. in the -80°C unit. Samples are being continuously added with the ongoing second follow-up. While the established infrastructure provides safe and sustainable storage of over 20 million samples, the single tube picking performance capability needed to be enhanced to meet future demands. The -180°C cryostorage technology will be supplemented by a fully automated sorting technology (Askon GmbH, Gera, Germany), which equips the Biorepository for upcoming large retrieval projects and increases storage capacity for the samples of the second follow-up. With this technology, we will relocate samples to high-density racks and establish single-type sample series. By adding this novel sorting technology, Helmholtz Munich completes the globally unique NAKO biorepository providing safe and highly efficient cryo-storage of NAKO biosamples and optimal accessibility of samples for innovative research.

How automation can make biobanking an assembly line

by Laeremans Hilde | Lifelines

Topic: 3C: Biobank Automation: Challenges, Opportunities and Solutions
Presenter Name: Laeremans Hilde
Keywords: Automation - green biobanking - large scale studies

Lifelines is a large, multi-generational, prospective cohort study that includes over 167,000 participants from the northern population of the Netherlands. Through the length, size and in-depth examination Lifelines provides excellent opportunities for studies worldwide unravelling the aetiology of multifactorial diseases focusing on multifactor risk factors.

To open the biobank for large-scale research projects, Lifelines needed to examine the process of data and bio sample collection and release. To meet the turn-around-times and high-quality requirements of scientific research, Lifelines has focused on a far-reaching form of automation. The lab and storage were set up to realize large sample projects in a short time with high quality and a minimum of human resources.

Lifelines started together with third parties', the development of biobank specific automation for sample reception through pipetting and DNA extraction, storage until the release for research. This flow exists out of different machines that are where possible connected physically but always on IT level, to arrive at a high-quality level sample preparation workflow.

The installation, validation and optimalisation is however a continuous process. The through-put has increased immensely with a steep reduction of labour costs and turnaround-time. Further optimalisation will be focussed om increasing the quality of the DNA extraction and decreasing process time. In the meanwhile, different projects are set-up to make Lifelines a green biobank by optimalization of the storage space, switching colling systems and optimalisation of the automated store.

This automation to the highest level improves quality and reduces turn-around-time and guarantees quality and makes Lifelines ready for the future.

High-Throughput Nucleic Acid Extraction in Biobanking: Performance Assessment of the chemagic™ Prime™ System in Large-Scale Population Studies

by Catherine Goh | Janina Gerhards | Niklas Joerres | Uwe Jaentges | Revvity | Revvity | Revvity | Revvity

Topic: 3C: Biobank Automation: Challenges, Opportunities and Solutions
Presenter Name: Catherine Goh
Keywords: automation, high-throughput, nucleic acid extraction, population genetics, sample prep

Large-scale population genetic studies face significant challenges in maintaining sample processing consistency and quality across diverse conditions. This summary evaluates the performance of the chemagic Prime automated nucleic acid extraction system in recent population cohort studies.

The system was utilized in several major studies, including the German National Cohort (NAKO) Health Study at Helmholtz Zentrum München[1], processing up to 200,000 buffy coat samples. Additionally, the CEPH Biobank in France employed the system for three population studies (POPGEN, MyPeBS, E3N Cohort)[2], extracting DNA from over 60,000 saliva samples collected in Oragene tubes over periods up to 10 years.

Extraction efficiency was assessed using spectrophotometric and fluorometric quantification. DNA integrity was evaluated through fragment analysis, while downstream applications included genome-wide association studies (GWAS) using Illumina genotyping arrays and whole genome sequencing (WGS).

The chemagic Prime, using M-PVA Magnetic Bead chemistry and customized protocols, achieved high DNA yields meeting required concentrations for 99.9 % of buffy coat samples and 96-97 % of saliva samples. GWAS success rates ranged from 98.9-99.1 % for saliva samples, indicating high DNA quality suitable for WGS and microbiota studies.

These results demonstrate the chemagic Prime system's robustness in high-throughput nucleic acid extraction for large-scale biobanking operations. Its consistent performance across diverse sample types, while maintaining highly pure nucleic acids and process traceability, makes it particularly suitable for extensive population genetic studies.

Improving blood phase separation on a Fluent liquid handling system (Tecan)

by Hélène Blanché | Nandhinie Zaneguy | Jean-Christophe Beaudoin | Laetitia Gressin | Valérie Morel | Jean-François Deleuze | Cyrille Andrianoff

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Topic: 3C: Biobank Automation: Challenges, Opportunities and Solutions
Presenter Name: Hélène Blanché
Keywords: DNA extraction, automation, blood fraction isolation, buffy-coat isolation, traceability

The isolation of blood fractions such as buffy-coat, plasmas and erythrocytes is a critical step for the subsequent quality of biological samples, both in terms of traceability and pipetting. This step, whether carried out manually by poorly trained operators or by unsuitable automated systems, can lead to a mixture of plasma and white blood cells, or white blood cells and erythrocytes. Poor buffy-coat isolation leads to lower-than-expected DNA extraction yields.

As part of the implementation of the French Cohort's Biobank (BioCF), the CEPH-biobank, ISO20387 and ISO9001 certified, is currently automating the isolation of blood fractions, on a Fluent liquid handling system (Tecan), and in particular the gentle separation of plasmas, buffy-coats and erythrocytes, in order to increase its capacity while guaranteeing the traceability and quality of samples.

The Fluent is equipped with a Phase SeparatorTM system, a pressure-based technology, which detects very precisely liquid-liquid interfaces and separates neighboring phases, while avoiding the risk of contamination.

The quality of the phase separation was evaluated after DNA extraction of each isolated phase (plasma, buffy-coat and erythrocytes). DNAs were extracted on a Chemagic Prime (Revvity) and quantified using the Quant-iT kit (Life technologies).

Encouraging preliminary results were obtained showing that more than 95% of the DNA extracted was in the buffy-coat phase but also highlighting the importance of the volume of the buffy-coat fraction.

Detailed data will be presented during the meeting, showing in particular the critical factors for obtaining the highest quality samples needed for further studies.

4C: Implementing and Securing Quality Control in Biobanking

Enhancing Biobanking Quality: Validation and Verification Strategies with Insights from the Leipzig Medical Biobank

by Ronny Baber | Juliane Weikert | Paula Bollmann | Berend Isermann | University Leipzig - Leipzig Medical Biobank | University Leipzig - Leipzig Medical Biobank | University Leipzig - Leipzig Medical Biobank | University Leipzig- Institute of Laboratory Medicine

Topic: 4C: Implementing and Securing Quality Control in Biobanking
Presenter Name: Ronny Baber
Keywords: Biobank processes, Validation, Verification

Introduction

DIN EN ISO 20387, the international standard for biobanking, outlines the requirements for quality and competence in the management of biological resources, including the validation

and verification of processes and methods. Both are critical to maintaining reproducibility, with validation assessing whether the specific requirements for the intended use have been met and verification confirming that the established criteria for the method have been met.

Methods & Results

The Leipzig Medical Biobank (LMB) has implemented protocols to improve the quality of biobanking processes and biobanked samples. Key processes and methods such as sample viability, DNA/RNA quantity, quality and integrity, and storage conditions were validated or verified according to DIN EN ISO 20387. As the quality of the samples must be appropriate for the purpose of the subsequent analytical procedures, various process- and samplerelated deficiencies were also addressed. In addition, the LMB carried out proficiency tests, which are mainly offered by the German Biobank Network and its associated partners.

Conclusion

The LMB demonstrates how its validation and verification strategy improves the quality of biobanking processes and biobanked samples. It is important to gain knowledge about the life cycle of biospecimens. In doing so, biobanks can be reliable partners for researchers by being able to answer unasked questions about factors that affect sample quality.

Monitoring of the Cold-Chain of Deep-Frozen Samples

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Topic: 4C: Implementing and Securing Quality Control in Biobanking

Presenter Name: Joerg Geiger

Keywords: Cold Chain, Frozen Samples, Sample Transport

Background

Transporting and handling of frozen samples are challenging tasks with temperature fluctuations often going unrecognized. While temperature loggers monitor packaging temperature, individual sample vials may experience significant variations due to nonuniform cooling, temperature gradients, and convection. During handling, the sample temperature can only be estimated or inferred from general assumptions. This study aims to develop a straightforward method to monitor cold chain maintenance during the transport and handling of deep-frozen samples.

Methods

Temperature changes are detected by observing the melting of test substances with distinct melting points, filled into the corresponding sample vials. Two methods were used: placing a miniature metal ball on the frozen test sample or placing a frozen drop of a test liquid on the frozen test substance. As the samples melt, the ball sinks or the drop of test liquid mixes with the test substance, indicating a temperature change.

Results and Conclusions
The method is inexpensive, easy to implement and calibrate, and utilizes the authentic sample format, ensuring it accurately reflects real temperature effects. It also reveals temperature variations based on sample position in the transport package The nonhazardous chemicals in the test substances pose no risk during transportation. This method enables the detection of temperature fluctuations during handling and transportation of frozen samples. Consequently, the method facilitates the validation of the processes involved in the transportation, receipt, registration, and handling of frozen samples. In addition the method enables the detection of deviations from the relevant guidelines or specifications.

Three Years of Proficiency Testing in Liquid Biobanking: A Proven Tool for Identifying Variations in Process and Sample Quality

by Sven Heiling | Alexander Funk | Michael Kiehntopf | Jena University Hospital, Institute of Clinical Chemistry and Laboratory Diagnostics and Integrated Biobank Jena, Jena, Germany | Carl Gustav Carus
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Topic: 4C: Implementing and Securing Quality Control in Biobanking
Presenter Name: Sven Heiling
Keywords: Contamination, NMR, Process assessment, Proficiency Tests

Background: Quality management principles are of paramount importance in ensuring sample integrity. Proficiency tests (PTs) are a valuable tool for quality assessment and assurance. The PT program for liquid biobanking has been running for three years, aiming to identify variations in process and sample quality across international and national biobanks.

Methods: The PT program involves multiple components designed to assess key aspects of liquid biobanking, sample entry control, processing times, sample homogeneity, and the precision of aliquot volumes. In the third version, a contamination test using nuclear magnetic resonance spectroscopy (NMR) was introduced in order to assess possible contamination by disinfectants in biological samples. In addition, for the first time, progress checks could be analyzed to monitor the accuracy and consistency of biobank practices.

Results: Here we present the findings of the recent PT conducted across 24 national biobanks. The results underscore the difficulties encountered in designing and implementing this PT framework, as well as the considerable variations in biobank processes that must be addressed to achieve further standardization. Progress checks highlighted improvements in standardized practices, but also identified areas needing further refinement, such as specific sample handling protocols.

Conclusions: The third PT marks a significant milestone, demonstrating that PTs are valuable tool for liquid biobank processes. The incorporation of NMR for contamination detection and progress checks have enhanced the ability to pinpoint variations in sample quality. The participation of 24 national biobanks underscores the increasing relevance

of the program in ensuring the reliability and consistency of liquid biobanks.

Enhancing Biobank Practices: Insights from EQA Participation at the IVO Biobank

by Cortell Granero, MI | Carretero Hinojosa, P | Ramirez Calvo, M | Mazcuñan Vitiello, T | Claramunt Alonso, R | López Guerrero, JA | Valencian oncology institute foundation | Valencian oncology institute foundation | Valencian oncology institute foundation | Valencian oncology institute foundation | Valencian oncology institute foundation | Valencian oncology institute foundation

Topic: 4C: Implementing and Securing Quality Control in Biobanking
Presenter Name: Cortell Granero Mª Isabel
Keywords: EQA

Introduction
External quality assurance programs (EQA) are valuable for evaluating work protocols and training. Although widely used in diagnostic laboratories, their significance in biobanking has grown with the adoption of the ISO 20387 standard. At the IVO Biobank, participation in EQA has revealed limitations but also driven improvements. This study aims to identify these limitations and propose enhancements to the biobank's quality management system.

Material & methods
Since 2020, the IVO Biobank has participated annually in various EQA, including RNA and DNA integrity (IBBL, 2020, 2021); DNA and RNA extraction from whole blood (IBBL, DNA BANK ISCIII, 2022, 2024); DNA extraction from FFPE and cfDNA extraction from plasma (EMQN ISO15189); RNA purity by spectrophotometry (IBBL, 2023); DNA and RNA extraction from frozen tissue (IBBL, 2023); and plasma isolation and aliquoting (German node Biobank, 2024).

Results
Each EQA involves receiving materials and applying routine protocols, with results or materials submitted to the EQA coordinator. Participation certificates and reports are issued upon completion. To date, the IVO Biobank has received 10 individual certificates, 11 general reports, 3 non-conformities opened, and 2 certificates without results.

Discussion and conclusion
Participation in EQA has highlighted limitations such as registration timing, costs, low participant numbers, analytical variability, the uncertain added value of certain EQAs, lack of accreditation or tailored improvement recommendations, as well as formal appeals processes. However, it has enabled detection of deviations in sample reception and improved shipment conditions. Despite these challenges, EQA participation has optimized several procedures, demonstrating the value of these programs.

FLOW CYTOMETRY AS A PROMISING TOOL FOR SAMPLE QUALITY CONTROL IN BIOBANKING

by Laura Valentina Renna | Lavinia Curini | Chiara Zara | Alisia Madè | Rosanna Cardani | Biobank BioCor, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy | Biobank BioCor, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy | Miltenyi Biotec SRLU Italy | Biobank BioCor,
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Topic: 4C: Implementing and Securing Quality Control in Biobanking
Presenter Name: Laura Valentina Renna
Keywords: biomarkers, flow cytometry, quality control

Introduction. Biobanks play a croucial role in research, providing high-quality biological samples and related data worldwide. Although quality controls (QC) are essential to ensure integrity of biological samples, specific and recognized QC have still to be defined. Biospecimen QC need to be optimized in terms of cost, amount of material necessary to perform the analysis, automatization and reproducibility. In this study we decided to design a QC program using a MACSQuant Analyzer 10 Flow Cytometer (Miltenyi Biotec), an automated instrument that allows event counting on every population.

Methods. Whole Blood, peripheral blood mononuclear cells (PBMCs), serum and plasma samples were processed in BioCor Biobank according to internal Standard Operating Procedures. The 8Color Immunophenotyping Kit was used to evaluate leukocyte subsets and viability in whole blood and PBMC. CD41, CD235a, CD71 and CD45 antibodies were used to evaluate serum and plasma composition. Cytokine expression was evaluated with MACSPlex Cytokine kit.

Results and Conclusions. A total of 3 different QC panels were defined: 1) SOP validation for plasma/serum separation and for PBMC isolation; 2) Evaluation of PBMC viability and determination of cellular subsets after cryopreservation; 3) analysis of different serum cytokines expression based on MACSPlex Capture Beads to assess specific pre-analytical variables. All QC analysis were preformed using a small quantity of biological material, ranging from 2 ul (platelet rich plasma) to 100 ul (whole blood). Express mode analysis allowed reproducibility between different users. Our experience indicates that flow cytometry could be a promising tool for sample quality control in biobanking.

5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics

Standardization of blood collection and processing in biobanking for EV research

by Paola Gasperini | Isabella Pesce | Lorena Pisoni | Nicola dalla Valle | Caterina Nardella | Francesca Demichelis | Manuela Basso | Vito D Agostino | Angela Bozza | Alessandro Cutarelli | Valentina Adami |

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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics

Presenter Name: Paola Gasperini

Keywords: Extracellular vesicles, SOP, plasma, quality controls

Introduction

With the support of the "Strengthening BBMRI.it" grant provided by Next Generation EU (Italian NRRP project code IR0000031 - CUP B53C22001820006), we had the opportunity to work toward the establishment of a new biobank for the collection of samples finalized for Extracellular Vesicles (EVs) research. At the University of Trento, we leveraged expertise and technologies available through the DiCIBIO Core Facilities and research groups collaborating in a community of practice.

While several biobanks advertise the availability of biofluids for EV research, they seldomly tailor their collection processes and quality controls to ensure the biofluids are fit for purpose (i.e., the validation of EVs associated biomarkers). The preanalytical phase may be an important source of artifacts in plasma samples if not properly handled. Indeed, both platelet activation and red blood cells (ref1) may release confounding EVs in the sample that interfere with the isolation of the vesicles of interest.

Methods

For this reason, to establish our standard operating procedures (SOP) on blood collection and processing, we reviewed position papers and guidelines for blood EV research supported by the International Society for Extracellular Vesicles (ISEV) and used the Technical Note (ref2) released by their Blood EV task Force to determine a minimal set of biofluid quality controls and their rigorous reporting.

Results and Conclusions

Here, we report on how three processing protocols affect hemolysis (assessed by spectrophotometer), residual platelet number (assessed by FACS), and lipoproteins (assessed by western blot and spectrophotometer) at plasma level and in matching plasmaderived EV samples from four healthy subjects.

Shortcomings in scientific studies assessing the fit-forpurpose of biobank biomaterials: the example of EDTA plasma for ccfDNA

by Hilde Brouwers | Jörg Hamann | Dorine Swinkels | Health-RI & BBMRI.nl, Utrecht, The Netherlands; 2Erasmus MC, Rotterdam, The Netherlands | Health-RI & BBMRI.nl, Utrecht, The Netherlands;

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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics

Presenter Name: Hilde Brouwers

Keywords: evidence-based, fit-for-purpose, standard

It is unknown if scientific reports that should form the evidence for evidence-based fit-forpurpose pre-analytical standards are appropriately designed for this purpose.

To increase our insights on this subject we made use of our experience in a Dutch national project, coordinated by Health-RI and BBMRI.nl. This project aims to establish an evidencebased, fit-for-purpose pre-analytic standard for EDTA plasma for the subsequent isolation of circulating cell-free (ccf)DNA.

A systematic literature search was conducted on predefined pre-analytic elements of this pre-analytic standard. To this date, 41 out of 122 selected articles were subjected to the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) scoring system (Guyatt et al, 2008). GRADE is a

widely adopted tool for grading the quality of evidence from clinical studies, which is used for making medical diagnostic recommendations. We used GRADE to assess laboratory experiments aiming to optimize pre-analysis.

The overall evidence obtained from the individual articles was low, which was mainly due to small samples sizes (n=<20 in 73%) and risk of bias because of limitations in the experimental set-up (46%). Even though some protocol elements were examined by many articles, such as blood collection tube type (54%) or delayed processing (66%), the experimental design widely differed between articles. These differences and lack of standardization in the reporting of results made it challenging to combine the findings of individual articles. Establishing and implementing experimental and reporting guidelines will be key to generate evidence-based pre-analytic standards.

Pre-analytical workflows for robust infrared profiling in blood-based disease diagnostics

by Frank Fleischmann | Guanting Guo | Jacqueline Aschauer | Tarek Eissa | Mihaela Zigman | Ludwig Maximilians Universität München, Faculty of Physics & Max-Planck Insitute of Quantum Optics | Ludwig Maximilians Universität München, Faculty of Physics | Ludwig Maximilians Universität München, Faculty of Physics & LMU hospital | Ludwig Maximilians Universität München, Faculty of Physics & Max-Planck

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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics

Presenter Name: Frank Fleischmann

Keywords: , Infrared spectroscopy, Pre-analytical factors, liquid biopsy

Fourier transform infrared (FTIR) spectroscopy is emerging as a promising analytical tool for liquid biopsy profiling. Infrared (IR) spectroscopy obtains information about the crossmolecular composition of complex biofluids, such as blood plasma, and generates a so called `IR molecular fingerprint' for each sample. Recently, we demonstrated the potential of IR molecular fingerprinting of plasma for cancer detection and health monitoring [1, 2]. Standardized pre-analytical sample handling is a cornerstone for ensuring reliable and reproducible analytical measurements. Here, we investigate various pre-analytical steps for their robustness against protocol variations.

Utilising 305 blood samples of 18 healthy study participants (DRKS-ID: DRKS00034935) as well as commercially available human sera, we investigate the full sample life cycle from venous blood sampling, blood processing, freezing, storage temperatures and thawing of plasma with focus on freeze-thaw-cycles to final sample handling prior to measurement. We determine the effect of protocol variations by means of differential spectra, principal component analysis and linear logistic regression in combination with receiver operating characteristics.

We demonstrate that improper/unstandardized handling of samples, particularly for excessive freeze-thaw cycles and improper filling of blood tubes, can lead to significant deviations in infrared molecular fingerprints, potentially compromising data reproducibility. Other factors, such as conditions of centrifugation for processing full blood to plasma, are robust and do not significantly affect data quality.

Our findings underscore the critical need for standardized preanalytical protocols to ensure reliable spectral measurements, minimize the potential of data bias in downstream analyses, and support the development of robust biophotonic, physico-chemical, and diagnostic applications.

Standardizing Saliva Collection: Key Pre-Analytical Factors for Reliable Research

by Daniel Alba-Olano | Inmaculada Almenara | Cecilia Sobrino | Víctor Fernández-Soria | Pilar Caro | Sergio Fernández | María-Jesús Artiga | CNIO Biobank (Spanish National Cancer Research Centre) |
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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics
Presenter Name: Daniel Alba-Olano
Keywords: Pre-Analytical Factors, cortisol, microbiome, saliva

The use of saliva samples for research is continuously growing due to their ease of collection and versatility in studying different analytes. Our study aims to define and control the pre-analytical variables affecting saliva samples for optimizing the conditions of collection and processing.

Firstly, we compared four standardized methods and commercial saliva collection tubes. We obtained analytical results of how cortisol, measured by ELISA assays, is collected by the different procedures, and quantified the amount of total, human and bacterial DNA obtained, by qPCR.

Secondly, we looked at the effect of both the pre-freezing storage time and temperature on the cortisol and the microbiome profile,to define the time that samples could be maintained before processing and freezing and the optimal temperature for this.For this purpose, we compared samples that were frozen at different times up to 24 hours, after we kept them both at room temperature and 4ºC. Then,we performed cortisol quantification by ELISA assays,plus DNA quantification, and NGS studies to search for the changes in the microbiome composition.

With our findings, we were able to standardize some of the processes involved in the collection and storage of saliva samples, quantifying the changes in the microbiome composition and cortisol detection due to temperature and time.Our results show the importance of controlling preanalytical variables, which affect the determinations of the samples. This will allow biobanks to design future longitudinal cohorts of high-quality samples for future research use,allowing the analysis of a wide range of analytes and the reproducibility of the studies conducted with them.

7C: Innovative Quality Concepts

Collaborative Initiative to a European Quality Manual for Biobanks

by Annemieke de Wilde | Josephine Uldry | Agnieszka Matera-Witkiewicz | Nhutuyen Nguyen | Belgian
Cancer Registry – BBMRI.be | Swiss Biobanking Platform (SBP) | Wroclaw Medical University Biobank | German Biobank Node (GBN) - bbmri.de

Topic: 7C: Innovative Quality Concepts
Presenter Name: Josephine Uldry | Nhutuyen Nguyen
Keywords: Biobanking, European, Handbook, Harmonisation, ISO 20387, ISO20387, International, National Node Collaboration, Quality Management Manual, Standardisation, Template

Introduction
The initiative for collaboration between QM coordinators of national nodes in Belgium, Germany, Poland, and Switzerland, as members of BBMRI-ERIC and ESBB, focuses on fostering a unified approach to quality standards. It aims to support a common strategy for quality management across the global biobanking network, harmonizing and improving quality practices worldwide.

Material & methods
The project leverages QM manuals (QMM) from Belgium, Germany, Poland, and Switzerland, aligning with international standards like ISO 20387, ISO 9001, ISO 19011, and ISO 27000. The overarching QMM will be reviewed by biobanking and ELSI experts for relevance and accuracy, excluding country-specific content (e.g. biobanking laws) to ensure broad applicability across jurisdictions.

Results
The initiative results in a harmonized QMM, aligned with international standards and made available as an open-access publication for global biobank accessibility. It also includes templates for biobanking documents and a glossary of key terms to ensure consistent quality management practices across the community.

Discussion & conclusion
The initiative of a harmonised QMM has been developed for utilisation by biobanks of all quality levels and across the globe, ensuring universal applicability. It is planned to include non-human biobanks, expanding the scope to a broader range of biobanking activities. The manual is consistent with the 10-year roadmap of BBMRI-ERIC, aligning with long-term goals and developments in biobanking. Additionally, it is to be regularly updated in line with new versions of relevant ISO standards, ensuring ongoing relevance and compliance with the latest international guidelines.

Management of human samples for observational and interventional studies in a hospital-integrated biobank: a dynamic framework with ISO 20387, GCP/GCLP standards and relevant legislation

by E. Cantarelli | L. Berardi | S. Chiappetta | G. Costanzo | E. Cristiano | M. Grossi | A. Karamanaj | V. Marinelli | N. Pagani | G. Passoni | F. Scalisi | L. Zito | C. Tresoldi | F. Ciceri | Centro Risorse Biologiche,
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Topic: 7C: Innovative Quality Concepts
Presenter Name: Elisa Cantarelli
Keywords: GCLP, GCP, ISO 20387, hospital

Introduction - The Biological Resource Center (CRB) is the institutional biobank of IRCCS Ospedale San Raffaele established with the aim of organizing, regulating and standardizing biobanking activities of human samples and associated data collected during observational and interventional studies, including phase I, in compliance with the requirements defined in ISO 20387, GCP/GCLP standards and relevant national legislation, e.g. Determina AIFA n.809/2015.

Methods and Results - The CRB coordinates the biobanking activities of 28 disease-driven sample collections and 76 observational studies according to OSR and CRB procedures and agreement between the principal investigator and the CRB for sample collection, transport, processing, storage and distribution. In 2024, the CRB managed biological samples collected during 106 interventional studies including 10 phase I and 10 phase I/II ongoing in 6 phase I clinical units and 1 lab self-certified for Determina AIFA n.809/2015 requirements. Moreover, since 2017, the CRB managed samples collected in 7 phase I and 10 phase I/II actually closed studies. According to the different study methodologies (observational and interventional), the CRB receives monitoring visits from CRO and CTC, internal GCP audits both for phase I studies and CRB activities, external audits from sponsors of clinical studies and inspections from competent authorities according to the protocol, GCP standards and relevant legislation, e.g. Determina AIFA n.809/2015.

Conclusions – Such approaches create a dynamic and effective framework and emphasize flexibility to adapt to the different quality requirements finally improving the way biological samples are collected, processed, stored and shared for translational research purposes.

Ensuring Biological Sample Quality through ACQA: A Novel Biobank Internal Quality Program

by Pauline Lambert | Geeta Acharya | Brian De Witt | Gaël Hamot | Estelle Henry | Saïda Mtimet | Lucie Remark | Olivia Roland | Kate Sokolowska | Pauline Torigny | Johanna Trouet | Wim Ammerlaan |

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Topic: 7C: Innovative Quality Concepts
Presenter Name: Olga Kofanova
Keywords: ACQA, Annual Control, Quality Assessment

As biobanks play an important role in supporting research and clinical studies, it is crucial to ensure that sample-processing methods are consistent, stable and of high quality. This presentation will focus on the development, design, and implementation of an internal quality control program in a biobank laboratory, aimed to optimize and standardize processing methods for a wide range of biospecimens. Our program addresses the collection of serum and plasma, extraction of nucleic acids from various sample types, including whole blood, buffy coat, FFPE and frozen tissue, stool, saliva, as well as cell-free DNA/RNA, and the isolation of viable PBMCs.

The focus of this internal quality program, named **ACQA** (**A**nnual **C**ontrol **Q**uality **A**ssessment), is to establish quality control measures and verifications of the major sample processing methods. This includes the use of specific collection kits, application of standardized operating procedures and/or work instructions, automated extraction systems, and annual performance reviews to monitor consistency and reliability. The assays are performed at regular intervals (e.g., monthly) for longitudinal performance assessment. We will also discuss how these practices have led to improved reproducibility, optimized protocols and minimized sample-to-sample variability.

Additionally, we will present and explain how our annual quality program can reflect the integration of new protocols and technologies into the biobank's operations. This extensive approach can assist the availability of high quality biospecimens for downstream research applications and support advancements of translational precision medicine studies. We will discuss future directions for ongoing quality improvements and applications across biobank laboratories.

A Complete Turnaround in Biobank Management: Innovations and Strategies

by Garcia-Molina, E | Silvente, A | Escamez, T | BioMedical Research Institute of Murcia Pascual-Parrilla

Biobank | BioMedical Research Institute of Murcia Pascual-Parrilla Biobank | BioMedical Research Institute of Murcia Pascual-Parrilla Biobank

Topic: 7C: Innovative Quality Concepts

Presenter Name: Garcia-Molina, Esperanza

Keywords: Action Plan, ISO 20387, Quality

Introduction

The rapid expansion of biomedical research coupled with the pursuit of a "One Health" approach necessitates that biobanks provide a coordinated and global response to an evolving science. In accordance with this preceding environment, the ISO 20387 standard establishes the overarching requirements for the competence, impartiality and consistent operation of biobanks.

Material & methods

Leveraging our experience as ISO 9001:2015 certified biobank since 2018, we have utilized the Self-Assessment Survey (SAS) instrument to develop an action plan for ISO 20387 compliance. Our biobank undertook a comprehensive evaluation to develop a new approach aimed at enhancing alignment with biomedical research needs and optimizing biobank efficiency.

Results

The analysis of this context has been carried out. The SAS analysis revealed key areas for improvement, including sustainability, monitoring, quality assurance, data interoperability and compliance with FAIR

principles. An action plan was developed in matrix form, prioritizing tasks for implementation. Strategic partnerships were established to improve response efficiency to external requests, in accordance with the organisation's commitment to quality.

Discussion and conclusion

Our goal is to achieve the BBMRI quality seal. The SAS proved an effective tool in identifying gaps and guiding improvements. Moreover, strategic collaborations were forged to enhance the effectiveness of responding to external requests.

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Recommendations for Repositories

ISO/IEC 27001 Information security, cybersecurity and privacy protection Information security management systems.Requirements • BBMRI_ERIC 10-year Roadmap

8C: Special Samples, Special Needs

Self-Assessment Survey for Microbiome analysis: ensuring quality and standardization in biobanks

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Topic: 8C: Special Samples, Special Needs

Presenter Name: Alice Bernardi

Keywords: CEN/TS 17626:2021, Microbiome, Self-Assessment Survey, biobanks, pre-analytical factors

The microbiota is a key mediator of several human functions, including metabolism, immune regulation and colonization resistance. Consequently, there is growing interest towards the potential exploitation of microbiome in clinical practice (1). However, multiple pre-analytical factors must be considered for handling microbiome specimens as they can severely impact the microbiome analysis (2). The European Committee for Standardization (CEN) therefore established Technical Specifications (CEN/TS 17626:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for human specimen - Isolated microbiome DNA) specifying requirements addressing these critical pre-analytical variables (3). The CEN/TS were developed by European experts in the context of the EU-project SPIDIA4P and led by BBMRI.at representatives. The document is mainly for the diagnostic medical field but is also highly relevant for biobanks and research laboratories. To validate biobank alignment with this European standard, we contributed to develop a SelfAssessment Survey (SAS) provided by BBMRI-ERIC, a pivotal tool in a certification perspective. The SAS consists of questions based on the CEN/TS and its pre-analytical requirements and recommendations for donor and specimen handling (collection, storage, transport, reception, microbiome DNA isolation, quality/quantity assessment, biobank storage). It includes different specifications

based on sample type (stool, saliva, skin and urogenital specimens), since each presents unique challenges in preservation, contamination control, and post-collection handling. Therefore, protocols must be customized and rigorously followed to ensure quality of microbiome analysis and biobanking. Ultimately, SAS is essential and made available for biobanks to standardize the microbiome pre-analytical workflow, ensuring consistency and reproducibility in microbiome studies.

A BBMRI biobank, as a third-party, guarantor for the institutional biobanking of Old Collections The BBMRI.it community, in dialogue with the Privacy Authority

by Sara Casati | Marialuisa Lavitrano | Manuel Ottaviano | Laura Milita | Simone Lapi | IEOMI_CNR BBMRI.it | BBMRI.it; UNIMIB | DPO - Area Metropolitana di Bologna | ISGI-CNR | U.O.C. Biobanche Azienda Ospedaliero Universitaria Pisana

Topic: 8C: Special Samples, Special Needs
Presenter Name: Sara Casati | Manuel Ottaviano
Keywords: Privacy Authority, accountability, biobank, community engagement, guarantor, old collections, third-party

In 2024, the BBMRI National Working Group "Hands on Old Collections" expanded to include additional research biobanks. The initiative now comprises 30 formally engaged research biobanks.

This collaborative effort and the consensus on established criteria and tools have fostered a climate of trust, resulting in a positive domino effect in mapping and stratifying old collections at the institutions hosting the biobanks.

The mapping process initiated a procedure to verify the quality of old collections. This significantly impacted raising awareness and empowering clinical and research staff and institutions about the importance of agreeing on a proper institutional biobanking process for old collections. It also highlighted the necessity of disposing of residual biological material that no longer meets the criteria for future research uses.

The collective outcome has catalysed a consensus action within the BBMRI community, including all biobanks, their respective DPOs, Citizen and Patient Organizations, and ELSI experts. The community has questioned the institutional role as a guarantor of BBMRI biobanks in activating institutional biobanking of old collections, identifying and agreeing on which specific key requirements must be present, and ensuring the verifiability of the biobank's accountability. Starting from this consensus, BBMRI.it has been opening an institutional dialogue with the Privacy Authority.

The Golgi Cenci Brain Banking protocol: an effective methodology for brain sampling and collection

by Alessandra Canazza | Chiara Calatozzolo | Annalisa Davin | Riccardo Rocco Ferrari | Giulia Negro | Arcangelo Ceretti | Antonio Guaita | Valentina Medici | Tino Emanuele Poloni | Department of Neurology and Neuropathology, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Laboratory of Neurobiology and Neurogenetics, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Laboratory of Neurobiology and Neurogenetics, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | School of Medicine and Surgery and

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Topic: 8C: Special Samples, Special Needs
Presenter Name: Alessandra Canazza
Keywords: Brain Bank, Neuropathology, longitudinal study

Introduction: Brain banking is a challenge in neuroscience. Our experience started in 2009, when a cohort study on brain aging in the town of Abbiategrasso - "InveCe.Ab" obtained ethical approval that includes brain donation. On this basis, we aim to propose an effective brain sampling method that permits multiple tissue analyses.

Materials and Methods: The Golgi Cenci protocol comprises a longitudinal multidimensional evaluation of donors. At death, the brain is extracted within 30 hours. The brain hemispheres, brainstem, and cerebellum are sampled, with alternating 1 cm sections fixed in formalin or snap-frozen in liquid nitrogen and stored at -80°C. Each fixed slice from one hemisphere corresponds to a frozen slice from the other. All brains undergo extensive characterization through morphological staining and immunohistochemistry, including assessments of major proteinopathies involved in neurodegenerative disorders, such as βamyloid, phosphorylated Tau, α-synuclein, and TDP-43.

Results: Unlike protocols that use one hemisphere for histology and the other for molecular analysis, ours requires fresh tissue cutting, offering key benefits: 1) no prolonged fixation; 2) characterization of both hemispheres; 3) omics studies on frozen samples with a histologically defined counterpart. Additionally, our brain samples come from subjects in a longitudinal study, linking neuropathological and molecular data to clinical, neuropsychological, biochemical, and genotypic evaluations.

Discussion and Conclusion: The availability of human brain tissue is essential for studying neurological diseases. To obtain reliable results, both tissue quality and the abundance of related information are crucial. We propose a methodology to achieve these goals and provide valuable research material.

10C: Samples Ready for Multi-omics Research

Unraveling Complex Disease Etiology: Insights from the Taiwan Biobank's Multiomics Data

by Chu, Hou-Wei | Yang, Hwai-I | Taiwan Biobank, Academia Sinica , Taipei, Taiwan | Taiwan Biobank, Academia Sinica , Taipei, Taiwan

Topic: 10C: Samples Ready for Multi-omics Research
Presenter Name: Chu, Hou-Wei
Keywords: Multiomics, Taiwan Biobank, Taiwan View

Introduction
The root causes of common diseases are multifactorial, involving genetics, environmental exposures, and lifestyle factors.

To address these complexities, the Taiwan Biobank (TWB) has developed a robust infrastructure to support biomedical research, aiming to enhance future health through a large-scale prospective study of the Taiwanese population.

Materials and Methods
TWB recruited 200,000 participants from the general population, with follow-up assessments for 70,000 and 8,000 individuals at the first and second stages, respectively. Data collection included questionnaires, physical examinations, biochemical tests, imaging studies, and biological samples (blood, urine, feces). Multiomics data included: Genomic Data: High-coverage whole genome sequencing (1,492 participants) and genotyping (150,000 samples), imputed using East Asian and Taiwanese-specific reference panels. Epigenomic Data: DNA methylation profiling (2,469 participants). HLA Typing: Highresolution typing (1,097 participants). Metabolomics: Analysis of 150 plasma metabolites (2,262 participants). Exposure Analysis: Urine plasticizer and melamine levels (1,799 participants). These datasets are accessible through Taiwan View, enabling phenome-wide association studies (PheWAS) across 242 traits.

Results
TWB has supported 580 research applications, resulting in 600+ international publications aligned with global biobank trends.

Discussion and Conclusion
TWB integrates multiomics data with electronic health records, offering a platform for biomarker discovery, disease mechanism elucidation, and precision medicine advancement. Its open-access model fosters collaboration, setting a global benchmark for populationbased research.

Multi-Omics Resources from the Faroe Islands: The FarGen 2 Project

by Leivur N. Lydersen | Katrin D. Apol | Olivia A. Gray | Melissa C. Hendershott | Laura Yerges-Armstrong | Kaja Wasik | Noomi Oddmarsdóttir Gregersen | FarGen, Faroese Health Authority | FarGen, Faroese

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Topic: 10C: Samples Ready for Multi-omics Research

Presenter Name: Noomi O. Gregersen

Keywords: FarGen, Genetics, multi-omics

Introduction: The FarGen 2 project builds on previous efforts to establish a genetic reference panel for the Faroese population by integrating multi-omics data. The project's objectives are to determine the genetic and molecular basis of the high prevalence of autoimmune and metabolic disorders in the Faroe Islands, such as type 2 diabetes, hypertension, ankylosing spondylitis, and inflammatory bowel disease, and to explore the genetic history of the Faroese population.

Methods: A total of 3,500 individuals have been recruited, providing biological samples for genetic, biochemical, anthropometric, metabolomic, and proteomic analyses. Participants also completed detailed questionnaires covering lifestyle, health, and environmental factors. Whole-genome sequencing (WGS) is underway, along with metabolomic and proteomic profiling. Planned analyses include genome-wide association studies (GWAS), metabolomewide association studies (mGWAS), and integrative approaches to link genetic variants with molecular and

phenotypic traits such as quantitative trait loci (QTL) and colocalization studies.

Results: Data generation and analysis are ongoing. The comprehensive integration of WGS, multi-omics datasets, and questionnaire data will provide an unprecedented resource for studying complex diseases, molecular pathways, and biomarkers in the Faroese population.

Discussion: While analyses are ongoing, FarGen 2 is positioned to impact healthcare in the Faroe Islands by enabling population-specific precision medicine. Furthermore, the project will generate insights with global relevance into the genetic architecture of disease and the evolutionary history of historically isolated populations, paving the way for novel diagnostics and therapeutic approaches.

On the road to diabetes: how biobanking-backed metabolomic digital twinning improves risk assessment and early diagnostics.

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Topic: 10C: Samples Ready for Multi-omics Research

Presenter Name: Dr. Diana Drettwan

Keywords: Metabolic profiling, big data analyses, diagnostic tests, digitalization, metabolomics, quality control markers

Diabetes is one of the major diseases of civilization with a high number of undiagnosed cases of type 2 diabetes. One of the aims of diabetes research is to diagnose the disease at an early stage, as the progression in the prediabetes stage can often be prevented by a simple change in lifestyle. In this context, a comprehensive characterisation of the metabolomic profile of prediabetes and diabetes patients could contribute to a better understanding of the development of type 2 diabetes.

The analysis of the metabolic constitution of more than 8000 participants from the LIFE Adult Study including healthy and diseased donors using lifespin's innovative NMR-based metabolomic profiling provides a deep insight into the link between genetic predisposition and individual health status with the development of lifestyle diseases such as type 2 diabetes mellitus at a population level. lifespin's holistic approach, i.e. the acquisition of more than 250 quantitative parameters per sample enables the generation of comprehensive metabolomic profiles for each sample. The identification of characteristic metabolite biomarkers and signatures that predict the development of type 2 diabetes leads to a major opportunity for diabetes risk assessment and improved early detection.

This approach requires detailed insights into the entire process chain, from sample collection and handling to biobanking. This is also made possible by the lifespin platform, and provides the presented valuable, sometimes surprising insights, correlations and challenges for and between different building blocks and players along the process chain.

Enhancing Multi-Omics Data Interpretation and Robustness through AI-Driven Digital Pathology

by Martina Betti | IRCCS Regina Elena

Topic: 10C: Samples Ready for Multi-omics Research
Presenter Name: Martina Betti
Keywords: digital pathology; immune deconvolution; endometrial cancer;

Introduction

Pathologists face challenges in analyzing complex images from limited tissue samples, moreover manual techniques are prone to variability and lack precision in describing intricate features. Histopathological image analysis, whether cell-level or region-based, benefits from robust AI models. Key challenges include model generalizability, explainability, and data quality constraints.

Material and Methods

We sequenced over 50 biobanked endometrial samples from different groups of patients: healthy, cancer patients and abortive patients. We performed a benchmarking of immune deconvolution on RNA-seq (via CibersortX) data by comparing estimated abundances to those detected in digitalized tissues. More specifically, we performed staining of CD4, CD8 and CD68 to assess tumor microenvironment (TME) topography (Infiltration Index) and immune scoring (area percentage) of the main immune populations involved in pregnancy and cancer. Estimates were obtaines though a concatenation of image augmentation and machine learning strategies.

Results

From a transcriptomic point of view, stronger immune activation and crosstalk was observed in the decidua compared to cancer, moreover tumors were classified into hot (n=9) or cold (n=11). From the imaging perspective, preliminary results suggest that tumor samples show higher Infiltration Indexes and overall abundance for those immune cells exhibiting CD4 and CD8 (mostly lymphocytes), while decidual samples show higher values for those cells exhibiting CD68 (Figure 1).

Discussion and Conclusion

RNA-seq provides high-resolution data but lacks spatial information and is dependent on methodology and material quality. Combining digital pathology with RNA-seq offers costeffective insights comparable to spatial transcriptomics, enhancing clinical relevance and understanding of immune activation and tumor microenvironments.

BIOMIS the italian human microbiota biobank ready to contribute to meta-omics applications

by De Palma, G | Bassotti, G | Reboldi, P | Ianiro, G | Gasbarrini, A | Nardelli, C | Cicinelli, E | Stasi, A | Pontrelli, P | Perrini, S | Giorgino, F | Losurdo, G | Moschetta, A | Tufaro, A | Zito, F.A | De Angelis, M |

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Topic: 10C: Samples Ready for Multi-omics Research

Presenter Name: De Palma, G

Keywords: Microbiome, Microbiota

Introduction

Recent studies highlight the key role of the human microbiota in health. Comprising billions of microorganisms, it influences immunity, pathogen defense, and intestinal development. Alterations in the microbiota are linked to various diseases. Despite growing research, the microbiota's exact role in disease progression remains unclear, limiting therapeutic potential. Therefore, the creation of a microbiota biobank (BIOMIS), the first in Italy, seemed crucial to us.

Material & methods

BIOMIS was developed through the collection of fecal, salivary, blood, urine, and vaginal samples from 737 individuals, including healthy volunteers and patients with diverse conditions such as antibiotic-resistant infections, metabolic, autoimmune, and oncological diseases, inflammatory bowel diseases, graft-versus-host disease, hepatic encephalopathy, kidney disease, recurrent cervico-vaginal infections, infertility, and endometriosis. Sample processing included cryopreservation (n=2,398) and aliquoting (n=4,957), with rigorous traceability and data management protocols.

Results

Despite the challenges posed by the COVID-19 pandemic, 737 subjects were enrolled, including healthy volunteers and patients. A part of biological samples from various centers were used to analyze microorganisms and the microbiota-disease relationship. The other samples (n=2,398) were cryopreserved and aliquoted (n=4,957), with traceability data recorded, allowing BIOMIS Biobank, located at the Bari Institutional Biobank, to become operational and included in the European BBMRI Directory.

Discussion and conclusion

The BIOMIS Biobank represents a strategic asset for microbiota research in Italy, enabling advanced meta-omic approaches, in vitro and in vivo studies, and fostering a deeper understanding of microbiota-disease interactions. Its potential clinical applications include supporting human microbiota transplantation and enhancing therapeutic strategies, paving the way for innovative solutions in healthcare.

7E: EP PerMed – Unlocking biobanks for personalised medicine

canSERV – providing cutting edge cancer research services across Europe and establishing a European Molecular Tumour Board Network

by Manuela Pausan | Enzo Medico | Andreas Türk | Konrad Lang | Judit Balogh | John Eriksson | Serena Scollen | Vitor Martins dos Santos | Bahne Stechmann | Michael Hagn | Corinna Brockhaus | Stéphane

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Austria | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria | EURO-Bioimaging, Turku, Finland |

ELIXIR/EMBL, Hinxton, UK | Wageningen University representing IBISBA, Wageningen, Netherlands | EU-OPENSCREEN, Berlin, Germany | ARTTIC, Munich, Germany | Instruct ERIC, Oxford, UK | EORTC, Brussels, Belgium | IARC/WHO, Lyon, France | INFRAFRONTIER, Neuherberg, Germany | EMBRC, Paris, France | ECRIN, Paris, France | Fundacio Privada Institut D'Investigacio Oncologica De Vallhebron representing Cancer Core Europe, Barcelona, Spain | EATRIS, Amsterdam, Netherlands | Universidade do Minho representing MIRRI, Braga, Portugal | ttopstart, Rijswijk, The Netherlands | University of Manchester representing ARIE, Manchester, UK | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria

Topic: 7E: Unlocking biobanks for Personalised Medicine
Presenter Name: Manuela Pausan
Keywords: cancer research, molecular tumour boards, precision medicine

Background: canSERV is a € 15 Mio. project offering cutting-edge research services, enabling innovative R&D projects and fostering precision medicine for patients benefit. canSERV involves 18 leading organizations across Europe including Research Infrastructures, key organisations and oncology experts.

Objectives: canSERV's main objectives are: offer at least 200 different unique, relevant and valuable cutting-edge services; establish a single, unified, transnational access platform to request services and trainings; ensure oncology-related data provided will be fully compliant with FAIR principles, complementing and synergizing with other EU initiatives; and, ensure long-term sustainability beyond project duration. Furthermore, canSERV establishes the European Molecular Tumour Board Network (EMTBN) that is open for anyone to join.

Results: The European Molecular Tumour Board Network is a network of experts that connects the MTBs of Clinical and Comprehensive Cancer Centres, pooling expert knowledge to enhance patient care globally. It operates through three main groups: Consensus Guidelines, Outcome Registry, and services for scientists and clinicians accessible via canSERV calls.

EMTBN Working Group 2 concentrates on establishing the MTB Outcome Registry to track patient outcomes, aiding therapy guidance, and research. The Registry will store pseudonymised data with consent under GDPR regulations. Initial efforts involved defining a data model based on existing MTB data models from 8 European countries. Experts from 20 European countries collaborated to define data features to be included in the Outcome Registry data model. The next phase involves populating the registry with patient cases, where consent permits.

Conclusions: canSERV is granted by the EU Horizon programme under #101058620.

Enriching the biobanks collections by refined data returned from previous projects – case study of T-cell receptor sequence data

by Johanna Mäkelä | Meri Lähteenmäki | Pauli Wihuri | Tom Southerington | Finnish Biobanks - FINBB | Finnish Biobanks - FINBB | Finnish Biobanks - FINBB | Finnish Biobanks - FINBB

Topic: 7E: Unlocking biobanks for Personalised Medicine
Presenter Name: Johanna Mäkelä
Keywords: Biobanks; Data return; personalized medicine

Introduction

The Finnish Biobank Act (688/2012, https://www.finlex.fi/en/laki/kaannokset/2012/en20120688.pdf) allows the data generated as part of a biobank research project to be returned to the biobanks. Returned data to biobanks, such as the T-cell receptor repertoire data, offers significant benefits in advancing biomedical research and improving clinical outcomes Additionally, returned data enables the development of personalized medicine approaches.

Materials & Methods

Here we showcase one use case on the data return process at the biobanks and the process of the re-use of the data. The data consists of approximately 6000 autoimmune disease patients T-cell receptor repertoire data originally generated as part of research collaboration with Adaptive Biotechnologies.

Results & Findings

The data was returned to the biobanks during 2024. The cohort is now available in Fingenious® services (www.fingenious.fi) and can be applied for other research projects. Currently the data is being used by academic researchers. This unique data set may enhance diagnostic capabilities for autoimmune diseases and provide answers to individual differences between treatment responses.

Discussion & Conclusions

The collaboration between biobanks and researchers, facilitated by returned data, fosters innovation and accelerates the discovery of new biomarkers and therapeutic targets. This collaborative effort is essential for advancing our understanding of complex diseases and developing novel treatments. Overall, the benefits of returned data to biobanks are multifaceted, contributing to improved diagnostics, personalized medicine, public health, and research innovation.

TRACK 4. Education, ELSI Insights, Stakeholder Collaboration and Patient-Centered Partnerships

3D: Empowering the Next Generation: Education and Training in Biobanking

Future in biobanking: a teaching course for biomedical students

by P. Manders | L.K. Schaecken-Klabbers | L.A. Sutherland | M.A. van den Brand | D.W. Swinkels | Radboud Biobank, Radboud university medical center, Nijmegen, the Netherlands | Radboud Biobank, Radboud university medical center, Nijmegen, the Netherlands | Radboud Biobank, Radboud university medical center, Nijmegen, the Netherlands | Radboud Biobank, Radboud university medical center,

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Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking

Presenter Name: Peggy Manders

Keywords: biomedical students, education, teaching course

Biobanks form the bridge between clinical research and clinical care and are an essential facility in a university medical center. However, this is uncharted territory for many researchers and clinicians.

To prepare students for a future in biobanking, the Radboud Biobank in Nijmegen, the Netherlands, has set up an annual 2-week course to provide biomedical bachelor

students with insight into the many facets of initiating a biobank collection from an interdisciplinary perspective. The course consists of interactive lectures and self-study assignments on biobanking and related topics, i.e. medical-ethical aspects, relevant pre-analytical aspects in clinical chemistry, pathology and genetics, and data management. To add practical and realtime knowledge, students are given a venipuncture course plus a tour of the lab including the central storage facility. Content experts present how their two long-standing collections are being utilized to improve medical care. The course focuses on reliability, comparability, generalizability and reproducibility of collection and handling of biological samples for future use.

During the course, students are required to write a protocol for initiating a *de novo* diseasespecific biobank collection. Assessment of the module is based on a written test (25%), protocol (50%) and a pitch about this protocol (25%).

So far, 90 students have completed the course. The education is positively assessed by participating students: i.e. the variety of facets as well as its applicability to setting up a biobank in practice are appreciated.

Advancing Biobanking Education: Updates and Insights from the new CAS in Biobanking a successful program designed in Switzerland open to an international audience

by Valeria Di Cola | Sabine Bavamian | Joséphine Uldry | Lou Ferraton | Louise Roy | Claudia Lagier | Michelle Rossier | Jean-Pierre Kraehenbuhl | Walter Reith | Julien Virzi | Hervé Bourhy | Carlo R. Largiadèr | Caroline Samer | Christine Joye | Jean Villard | University of Geneva | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform | HSeT Foundation | HSeT Foundation | HSeT Foundation | HUG, University of Geneva | Institute Pasteur | Inselspital, Universitätsspital Bern | HUG, University of Geneva | Swiss Biobanking Platform | HUG, University of Geneva

Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking
Presenter Name: Valeria Di Cola
Keywords: biobanking, education, governance, quality standards, sample management, training

The Certificate of Advanced Studies (CAS) in Biobanking, hosted by the University of Geneva in partnership with the Swiss Biobanking Platform, Institut Pasteur, and HSeT Foundation, is Switzerland's leading training initiative for biobankers. This program addresses the growing demand for specialized knowledge and skills in biobanking, enabling participants to establish and manage biobanks that meet the highest standards.

Designed to provide a stepwise learning experience, the program spans three progressive modules, combining e-learning and online lectures in English. Module 1 introduces the fundamentals of biobanking. Module 2 explores the implementation of biobanking processes, providing intermediate-level training for professionals managing biological samples. Module 3 focuses on advanced professional management, equipping experienced practitioners with cutting-edge insights.

In January 2025, the program launched its second edition with 20 international participants from diverse backgrounds. The upcoming third edition, promises to build on

this success, welcoming new participants to join the global community of biobankers. This CAS program plays a pivotal role in harmonizing biobanking practices across disciplines and fostering the development of highly skilled professionals. Together, we empower the next generation of biobankers to advance the field with comprehensive, tailored education.

For further details, visit www.unige.ch/formcont/en/courses/cas-biobanking or contact us at casbiobanking@unige.ch.

Updating domestic animal biobanks on cellular models - A training workshop

by Giuffra E. | Egidy-Maskos G. | Clark E. | Hartwig T. | Crooijmans R.P.M.A. | Sokolov A. | Robertson J. |

Cartik G. | Ige T.O | Brand-Williams W. | Tixier-Boichard M. | INRAE, GABI, Jouy-en-Josas, France | INRAE, GABI, Jouy-en-Josas, France | Univ. Edinburgh, Roslin, UK | FBN, Dummerstorf, Germany |

Wageningen University, The Netherlands | EMBL-EBI, UK | NMBU, CIGENE, Norway | EFFAB, Brussels, Belgium | INRAE, GABI, Jouy-en-Josas, France | INRAE, GABI, Jouy-en-Josas, France | INRAE, GABI, Jouyen-Josas, France

Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking

Presenter Name: Tixier-Boichard M.

Keywords: cellular models, domestic animals, training

Introduction: EuroFAANG RI (https://eurofaang.eu) is an INFRA-DEV project funded by the Horizon Europe research framework, which develops the concept of a new infrastructure to support Genotype-to-phenotype (G2P) research for domestic animals. Our 2023 survey identified a subset of animal biobanks willing to integrate in vitro cellular models in their collections. This integration raises new issues for biobanks. A training workshop has been organised to address these issues and harmonize procedures (https://eurofaang.eu/g2p-in-a-dish).

Methods: The EuroFAANG hybrid workshop "G2P in a Dish" held by INRAE in the Jouy-enJosas campus (France) gathered the European Animal Science community to unlock the potential of cellular model systems and genome editing tools in farm animals research and applications, in line with the ethical principles of the 3Rs (reduce, refine, replace) for animal experiments. EFFAB disseminated the program which covered 4,5 days, with 17 talks, 6 practical sessions and 2 roundtable discussions. Applications were evaluated by experts based on experience and a motivation letter.

Results: Nineteen trainees were selected from 8 European countries: 7 PhD students, 2 post-docs, 5 academics (research and higher education), 4 engineers or technicians and 1 biobank manager. All of them followed the practical sessions devoted either to Crispr-Cas9 design, to metadata standardization of cellular models or single-cell data analysis; 15 were trained on tissue processing, 16 on culture, transfection and imaging of either pig organoids, or fish cell lines.

Discussion: Take-home messages were delivered to enhance applications of *in vitro* G2P research in complementarity with *in vivo* experiments, taking advantage of biobanking options.

Developing tools for education in biobanking: the “SCIence outreach: The example of BIObanks in Europe” ERASMUS+ project

by Vasileios L. Zogopoulos | Deborah Mascalzoni | Roberta Biasiotto | Tom Southerington | Tarja Salmi-

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Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking

Presenter Name: Olga Tzortzatou-Nanopoulou | Vasileios L. Zogopoulos

Keywords: biobank, biobanking, education,

gamification, online course, public, science

outreach, serious game, students, young scientists

Introduction

Biobanks rely on public trust and active citizen participation. To enhance public awareness of biobanks and biobanking, and encourage wider societal engagement, educational initiatives are crucial. Even students and researchers often require deeper knowledge about biobanking to inform patients and research participants. The “SCIence outreach: The example of BIObanks in Europe” (SCIBIOEU) project affiliated with BBMRI-ERIC, in five European countries (Austria/BBMRI.at, Cyprus, Finland, Greece, Italy), aims to address this need by developing an online course for students of higher education institutions and young/early-career scientists, and a serious game for the public.

Material & methods

We mapped the current state-of-the-art on biobanking-related courses and serious games. Through an empirical approach, we collected selected stakeholders’ views and needs (including students, professors, researchers, developers, designers, biobanking professionals). Based on these methods, we created an online course and serious game in Moodle and Unity, respectively, using a collaborative approach to develop their content.

Results

An online multimedia course incorporating texts, videos, and user self-evaluation mechanisms, was developed. Additionally, a 3-

D online adventure-type serious game that navigates users through a virtual biobank, was designed. Finally, an LLM-model trained on biobanking-related open-access material, was created as an auxiliary tool for users.

Discussion
By developing two freely accessible resources addressing the needs of different target groups, SCIBIOEU, an ERASMUS+ funded initiative, seeks to strengthen science-society communication, through the example of biobanks. These tools aim to foster greater understanding and trust in biobaking, ultimately supporting active participation.

4D: Balancing Ethics and Innovation: ELSI in Biobanking

Co-creating the informative BBMRI.it “ecosystem” for the next-generation biobank. Integrated consent matrices, as the backbone of the BBMRI app, full recognition of the biobank as guarantor of rights, principles and processes, digitized publicity of biobank activities

by Sara Casati | Matteo Macilotti | Laura Milita | Raffaele Conte | Sara Gibertini | Eva Pesaro | Rosanna Cardani | Marialuisa Lavitrano | IEOMI_CNR - BBMRI.it | Trento University | ISGI-CNR | IFC-CNR |

Neuromuscular Disease Biobank (NeuMD-Besta) - IRCCS Besta Foundation | AISP Associazione Italiana

Sindrome di Poland | BIOCOR, IRCCS San Donato | BBMRI.it; UNIMIB

Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking

Presenter Name: Sara Casati

Keywords: BBMRI APP, BIMS, ELSI metadata, accountability, biobank, particpatory consent, transparency

Since July 2024, 2 national ELSI BBMRI.it working groups have been working synchronously to build a digitized in-formative framework for next-generation biobanking. This framework aims to be sustainable and coherent for potential participants of biobanking, as well as for all parties accountable in the biobanking process, including biobanks, Research Ethics Committees, and Data Protection Officers

Each biobank participates with its DPO in a cocreation process involving representatives of citizens and patients and ethics committees.

Key challenges include:

1. Updating the "National Matrix for an Informed Consent Process to Research Biobanking" (shared as CC04 https://repository.bbmri.it/s/stC8Lc4kPDn2qQt) given the BBMRI APP finalization. The BBMRI APP acts as a proactive vector between potential participant and biobank utilizing a Conditions of Use-based digital workflow that introduces consent options, incorporates ELSI metadata into the digital characterization of biological materials, and integrates these into the Biobank Management System - BIMS.
2. Proposing a community initiative with the Privacy Authority so that the current regulatory framework, which mandates re-consent for each distribution of biobank samples, is superseded by the complete acknowledgement of Research Biobank as the guarantor of principles (transparency, inclusion, accountability, lawfulness, proportionality, etc.),

citizens' and researchers' rights, and processes, thanks to the digitized information ecosystem.

Key components include the BBMRI APP, where participants can dynamically exercise their rights, and the biobank public page, which will provide access to ELSI and governance tools, along with an updated list of protocols and processing data disclosures, positively evaluated by the biobank's access committee.

An embedded ethics approach to trustworthy AI for transformative healthcare

by Melanie Goisauf | Mónica Cano Abadía | BBMRI-ERIC | BBMRI-ERIC

Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking

Presenter Name: Melanie Goisauf | Mónica Cano Abadía Keywords: ELSI, Ethics of AI, datafication, embedded ethics, trustworthy AI.

Introduction

The increasing datafication in the life sciences, coupled with advancements in artificial intelligence (AI), is transforming medical knowledge production. Biobanks, as critical infrastructures for data sharing, play a pivotal role in supporting these data-intensive research practices. However, integrating AI into healthcare raises ethical and societal concerns, particularly around transparency, fairness, and equity, necessitating a focus on trustworthy AI.

Methods

This presentation draws on outcomes from interdisciplinary projects and empirical data on trustworthy AI and biobanking. These are complemented by theoretical perspectives from social sciences, humanities, and law, providing a comprehensive approach to analyzing trust and trustworthy AI in medical contexts.

Results

Findings reveal that the "data turn" in life sciences has reshaped infrastructures originally designed for sample management into predominantly data-centric systems. AI-driven technologies are at the forefront of these developments, introducing both opportunities and challenges. Key insights emphasize that trustworthiness in medical AI requires collaborative efforts throughout the AI lifecycle, including consideration of human, systemic, institutional, and societal factors. In our presentation we draw on lessons learned from several medical fields to suggest guidelines on trustworthy AI implementation in the context of biobanking (Akyüz et al., 2024; Goisauf et al., under review).

Discussion

A human-centered, multi-stakeholder approach, emphasizing transparency, ethical robustness, and equity, is essential. By integrating these principles through an embedded ethics approach, infrastructures can foster trustworthy AI, enhancing both the credibility and utility of AI-mediated healthcare systems.

Electronic Consent - the key to compliant, secure and efficient biobanking

by Joerg Geiger | Michael Neumann | Roland Jahns | Interdisciplinary Bank of Biomaterials and Data Wuerzburg (ibdw), University and University Hospital Wuerzburg, Wuerzburg, DE. | Interdisciplinary Bank of Biomaterials and Data Wuerzburg (ibdw), University and University Hospital Wuerzburg,

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Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking

Presenter Name: Joerg Geiger

Keywords: electronic signature, informed consent

Background

Informed consent is an essential requirement for human biobanks. In most cases, informed consent is currently obtained on paper, which poses a significant risk of transmission errors and delayed availability due to manual documentation procedures. The transition to electronic consent has the potential to simplify these processes and to increase their efficiency.

Methods

The basic requirements for the consent procedure are independent of the technology used. All aspects of the use of the samples and data, as well as possible consequences and risks have to be presented comprehensively and understandably. The documentation of consent is of particular importance, since the biobank is obliged to prove that the consent has been lawfully obtained and is meeting ethical requirements. To substantiate the legitimacy of consent, it is imperative that the "direct and unambiguous action" of the donor be executed in a manner that is readily traceable and clearly attributable to the donor. In the context of electronic device signing, this objective can be accomplished by registering biometric parameters of the signing procedure.

Conclusion

Electronic consent procedures are strongly recommended for biobanks to meet the requirements for a reliable documentation of donor consent and to prove legitimate ownership of samples and data (in any case). Electronic consent provides numerous benefits, including improved reliability, security, and trust in biobanking activities. It simplifies processes for clinical staff and provides machine-actionable information about the conditions in the consent. As biobanks modernize, electronic consent is a critical tool for optimizing the operation of biobanks.

How will the new WHO and WMA guidance policies impact biobanking, individuals and communities?

Mascalzoni D, Eurac Research, Bolzano Italy , Uppsala University, Uppsala, Sweden

by Deborah Mascalzoni | EURAC Reserch and Uppsala University

Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking

Presenter Name: Deborah Mascalzoni

Keywords: New policies, WHO, WMA

Introduction: ELSI for biobanks needs to account for the new WMA Helsinki Declaration and the WHO Guidance on Human Genomic Data . Both instruments fucus not only on individuals but also groups and communities' rights more widely. This shift may have a significant impact on how we approach data and bio-samples governance.

Materials and methods: WMA Helsinki Declaration and WHO Guidance on Human Genomic Data have been analysed in light of current ELSI approaches for biobanking, looking specifically at the potential implications for the governance of biobanking. Special attention was given to Individual rights vs. community rights, governance and oversight beyond individual consent, access and sharing of resources.

Results: WMA and WHO attempt to raise awareness to avoid discriminatory practices that in turn might have a negative translational potential and will lead to inequitable resource access. The WHO guidance emphasises the need to account for data throughout their lifecycle. Community interests that go beyond the individual's, fair approaches to the access and use of resources, respect for individuals and communities and solidarity are guiding principles for a more equitable system.

Discussion: current governance of biobanking, based on individual rights and Institutional interests, rarely engages communities beyond recruitment phase. Considering instead the whole lifecycle of biosamples and data might be impactful. Including the community's interests in the discussion could translate in new conditions for DTAs, benefits sharing etc. A wider discussion in the biobanking and scientific community is necessary to translate theoretical reflection into fair practices.

5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability

Towards sustainable biobanking by increasing researchers' financial contribution

by P. Manders | L.K. Schaecken-Klabbers | L.A. Sutherland | M.A. van den Brand | D.W. Swinkels | Radboud Biobank, Radboud university medical center, Nijmegen, the Netherlands | Radboud Biobank, Radboud university medical center, Nijmegen, the Netherlands | Radboud Biobank, Radboud university medical center, Nijmegen, the Netherlands | Radboud Biobank, Radboud university medical center,

Topic: 5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability
Presenter Name: Peggy Manders
Keywords: business model, ethical, financial, organizational, sustainable

The Radboud Biobank (RB) was established as the central biobank facility at Radboudumc in Nijmegen, the Netherlands, to support translational research. Since its establishment in 2012 all costs for processing, storage and management of biological material were for the RB's account. Researchers only paid a fee to take out samples. This funding model was no longer considered sustainable since the number of samples issued in practice fell short of expectations necessitating financial and organizational changes.

The aim was to improve sustainability by creating incentives for biobank collections to be critical about what, and for what purpose, they collect biological samples. To this end, an independent committee, consisting of Radboudumc researchers, financial and risk management experts, defined changes needed to make the RB financially, ethically, and organizationally sustainable. Last summer, the Radboudumc Board of Directors approved the final business model and associated policy.

In this model, Radboudumc researchers are obliged to include biobank collections in the RB, to improve efficient use of infrastructure and state-of-the-art methodology, unless this is not possible for operational reasons. Researchers pay for half of sample processing costs and for storage. For issuance of samples, a graduated rate per sample is used and labor costs are invoiced.

To assist existing biobank collections with financial planning a 3 year transition phase exists, starting as per January 1st, 2025.

Swiss Biobanking Platform's switch from a service development to a service utilization platform

by Christine Joye | Sabine Bavamian | Swiss Biobanking Platform | Swiss Biobanking Platform

Topic: 5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability
Presenter Name: Christine Joye
Keywords: Empowerment, One-stop-shop, Quality, Sustainability, stakeholder engagement

Aligned with BBMRI-ERIC's strategic vision, Swiss Biobanking Platform (SBP), the biobanking research infrastructure of national importance, is thrilled to announce that the Swiss National Science Foundation (SNSF) has renewed its support for the 2025–2028 period.

This upcoming period is the opportunity for SBP to switch from a service development platform to a service provider infrastructure, but also to join forces at the European level enabling researchers benefit from high-quality biobanks and securing the future for biobanks.

Together, we're shaping a future focused on innovation, collaboration, and impactful research across Europe based on the following pillars and strategic objectives :

- Quality : Exploitation of a tailored quality strategy for biobanks with dedicated tools and consulting services, integrating the One Health approach, to promote standardization and FAIRifcation of samples and data.
- Sustainabilty : Development of a one-stop-shop model for researchers as well as innovative collaboration models to support biobanks in their daily practice.
- Biobank and researcher empowerment : Shaping communication, education and collaborative training for different target groups, such as researchers, data managers, project managers and biobank technicians
- Stakeholder engagement : Srengthening its biobank leadership role by increasing multisectoral engagement with stakeholders including local, national and European communities to generate further socio-economic impact and awareness.

Using the robust structure and services developed from its creation in 2016 for biobanks, SBP works on innovative concepts to facilitate access to samples and assess impact on research both nationally and at the European level.

Developing a Cost Visualization and Calculation Tool for Sustainable Biobanking by the Diverse Biobank Organizations in Belgium

by Manon Huizing | Elke Berneel | Annelies Debucuoy | De Wilde Annemieke | Stephanie Gofflot | Johan Guns | Maxime Lorent | Loes Linsen | Pieter Moons | Liselot Mus | Caroline Rombouts | David Triest |

Kimberly Vanjhees | Van Den Heuvel Rosette | Alexandra Vodolazkaia | Maartje Van Frankenhuijsen |

Biobank Antwerpen, Antwerp University Hospital & University of Antwerp, Belgium | Biobank University

Hospital Gent | Belgian Cancer Registry, Brussels | Belgian Cancer Registry, Brussels | Biothèque

Hospitalo-Universitaire de Liège, CHU de Liège | Central Biobank, UZBrussel | BruTus Oncology, CHU

Brugmann | UZ/KU Leuven Biobank, University Hospitals Leuven | Biobank Antwerpen, Antwerp

University Hospital & University of Antwerp, Belgium | TEARDRoP – PHO biobank, Department of Pediatric Hematology, Oncology and Stem Cell Transplantation, University Hospital Gent/ BSPHO | Biobank Institute of Tropical Medicine, Antwerp | Central Biobank Platform Sciensano | University Biobank Limburg | Biobank VITO | Central Biobank Platform Sciensano | Biobank Institute of Tropical Medicine, Antwerp

Topic: 5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability
Presenter Name: Manon Huizing
Keywords: biobank costs, cost calculator

Introduction

Biobanks in Belgium have different organisational profiles that influence their business model. Within the BBMRI.be sustainability working group, a tool has been developed to visualise the costs associated with biobanks. This will enable them to share these financial insights with researchers as well as the institutions management and help the biobanks (non-profit structure) with transparent reimbursement of their biobank costs.

Methods

Costs were grouped into three main categories: personnel costs, Biobank Information Management System (BIMS)-related costs and storage/processing costs. For each category, a list of associated costs was included in the calculator tool. By including the total number of new primary samples per year and the total number of samples in storage, a total cost per sample can be calculated for personnel, BIMS and storage costs respectively. The final calculations of the tool provide biobanks with an indication of the real costs per sample in their biobank.

Results

The tool was validated by ten biobanks in the BBMRI.be network, with different types of organisational structures and strategies, including biobanks with disease-specific collections linked to (university) hospitals and biobanks focusing on population cohorts linked to government organisations. Preliminary analyses showed large differences in costs between biobanks, depending on their type and size.

Conclusions

The final analyses of this exercise will make biobanking-related costs in Belgian biobanks more visible and transparent and will enable more sustainable biobanking. Their inclusion in a calculator tool will allow to optimise cost recovery from researchers and reporting of total costs to institutional management.

Enhancing Sustainability through Industry Collaboration: Insights from the Czech Experience

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Topic: 5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability
Presenter Name: K. Nováková
Keywords: Czech experience, industry collaboration, sucess story, visibility

Introduction:

Due to the decreasing financial support allocated for LRIs provided by the government of the Czech Republic, it is only a matter of time when the operation and functioning of each LRI will be more or less referred to its own resources. However, it is necessary to have already prepared a crisis solution to overcome the lack of funds, e.g. financial contribution from the parent institution, costs coverage by

research projects or as a fee-based services provided by biobanks to industry.

Results:
In order to ensure the sustainability of BBMRI.cz and to cover the costs associated with the operation of the infrastructure, we have responded to this fact by increasing our involvement in research projects (currently more than 30 scientific projects). In addition, due to the increasing interest of the commercial sector in applied biomedical research in the Czech Republic, including services provided by biobanks, we focused on improving the visibility of biobanks through connection to European online tools, enhanced interaction with the professional and general public and an expanded portfolio of services offered.

Conclusion:
The number and duration of a biobank's collaborations with a particular commercial entity reflect the overall approach of biobanks and the satisfaction with the services offered and/or provided. It is the complex ability to implement the necessary ELSI measures and a sufficient range of professional services that can help biobanks to become a valid partner for industry in the field of biomedical research. This contribution was supported by LM2023033 and by EU HE No. 1101131701 (EvolveBBMRI).

7D: Patient-Centric Biobanking: Strategies for Engagement and Participation

Digital Transformation in Biobanking: The Implementation of eConsent at the Valencian Institute of Oncolgy (IVO) Biobank

by Cortell Granero MI | LLavata Mayordomo A | Novella Cañadas R | Martínez Esteso J | López García P |
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Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation
Presenter Name: Mª Isabel Cortell Granero
Keywords: econsent

Introduction
Informed consent (IC) is essential in biobanking to ensure ethical and legal compliance while respecting donors' will. Enables participants to know and decide about the use of their samples and biological data for biomedical research. Properly obtained consent enhances transparency, builds trust, and supports future studies through ethically sound sample utilization. With evolving regulations and participant rights (e.g., consent withdrawal), digital solutions like eConsent are vital for efficient management. This study describes the implementation of eConsent at the IVO Biobank.

Material & method
The Clinical Documentation and Admissions Unit (UDCA for its acronym in Spanish) includes an administrative module in the electronic medical record system for document management and biometric signatures. Utilizing this workflow, we integrated the

Biobank eConsent, whose document complies with the legal requirements When a patient's medical record is opened, and after being informed by healthcare administrative staff, the signature process is activated via tablet. The signed consent is electronically recorded, allowing consultation, PDF generation, and classification as declared, revoked, or physically signed.

Results

Since its implementation in mid-2021, 18,554 accepted consents have been signed, with 160 revocations (0.85%). The IVO Biobank developed a brochure explaining translational research and the use of biological samples and clinical data, provided to patients at the time of eConsent signing. **Discussion and conclusion**

eConsent implementation has improved IC management, reducing administrative workload, facilitating processing, enhancing version control, and optimizing sample transfers through centralized, accessible records. It has also enabled effective revocation tracking.

The challenge of building cohorts beyond hospital walls

by Daniel Alba-Olano | Cecilia Sobrino | Inmaculada Almenara | Virginia López | Jonathan Moro | Nuria Ajenjo | Pilar Caro | Sergio Fernández | Elena Molina | Carmen Ortega | María-Jesús Artiga | CNIO Biobank (Spanish National Cancer Research Centre) | CNIO Biobank (Spanish National Cancer Research Centre) | CNIO Biobank (Spanish National Cancer Research Centre) | sociación Española de Tripulantes de Cabina de Pasajeros (AETCP) (Spanish Cabin Crew Association) | sociación Española de Tripulantes de Cabina de Pasajeros (AETCP) (Spanish Cabin Crew Association) | CNIO Biobank (Spanish National Cancer Research Centre) | CNIO Biobank (Spanish National Cancer Research Centre) | CNIO Biobank (Spanish National Cancer Research Centre) | CNIO Biobank (Spanish National Cancer Research Centre) | CNIO Biobank (Spanish National Cancer Research Centre)

Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation
Presenter Name: Daniel Alba-Olano
Keywords: Best practices, Cohorts, Community engagement

Building robust and representative cohorts is essential to advancing biomedical research. This task is particularly complex for a biobank in a research centre not associated with a hospital. However, at the CNIO Biobank, we have succeeded in creating longitudinal cohorts of high scientific interest, being the most outstanding one of a professional collective.

To achieve this success, it has been crucial to sensitise ourselves to the collective's concerns and engage directly with their community, thus creating a bond of trust and transparency. Furthermore, we have allowed the members of this collective to actively participate in decision-making from the beginning of the project and continue to do so today, four years later, always encouraging and facilitating their participation. Finally, the close relationship between biobank staff and donors has allowed us to build donor loyalty year after year.

On the other hand, the biobank's efforts to raise awareness of the cohort in scientific dissemination activities, develop collaborations with researchers, as well as the donors' word of mouth, have allowed them to feel part of the problem and strengthen their commitment.

As a result, we have been able to create a growing cohort of donors each year, collecting thousands of human samples of five different types and comprehensive data. These samples are already being used in three research projects. Moreover, as they are managed and processed entirely in our biobank, we have the security of obtaining reliable data and controlled pre-analysis of the samples, ensuring the high quality and reproducibility of the studies.

Evaluation and lessons learned regarding the ABOARD cohort panel: a citizen panel advising on an Alzheimer's disease cohort study

by Miriam Beusink | Tanja J. de Rijke | Kyra K.M. Kaijser | Marlon Smeitink | Marja Berkhout | Lidwien Kroon | Tieneke B.M. Schaaij-Visser | Sophie van der Landen | Dirk-Jan Saaltink | Els van der Rhee |

Susanne Rebers | Casper de Boer | Hanneke Rhodius-Meester | Wiesje van der Flier | Leonie Visser | Health-RI and Netherlands Cancer Institute | Amsterdam UMC | Amsterdam UMC | ABOARD cohort panelist | ABOARD cohort panelist | ABOARD cohort panelist | Lygature | Amsterdam UMC | Dutch Brain

Foundation | Dutch Brain Foundation | Health-RI and Netherlands Cancer Institute | Amsterdam UMC |

Amsterdam UMC | Amsterdam UMC | Amsterdam UMC

Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation

Presenter Name: Miriam Beusink

Keywords: PPI, Patient Engagement Quality Guidance, dementia, panel, public involvement

Introduction

Public involvement in research is becoming increasingly relevant. However, a formal systematic evaluation of PI is often lacking. This study assesses the quality of a PI panel within an Alzheimer's disease cohort (ABOARD), and identifies lessons learned.

Material & methods

The panel consists of 49 people who advise the cohort through questionnaires and live meetings, under independent coordination. This ensures that the cohort aligns with participant needs, e.g., regarding consent information, data collection and data issuance. The panel is evaluated using questionnaires among panelists and cohort-researchers, covering questions inspired by the Patient Engagement Quality Guidance tool.

Results

Response rates were 37% for panelists (16/43) and 67% for researchers (4/6). Most panelists indicated that the goal of the panel (95%) and communication (94%) were clear and that they had enough resources to participate (75%). Transparency was sufficient (87%). All panelists indicated that they felt respected and that it was easy to participate in online questionnaires. Participation in live meetings was considered difficult (56%), mostly due to work, time or travel constraints.

Researchers highlighted improvements in communication to cohort-participants and being able to quickly make concrete changes due to panel feedback as positive impact. Researcher-identified elements for improvement comprised engaging in more expectation management towards the panel (e.g., expected number of participants in a live meeting).

Discussion

The structure and set-up of this panel, providing feedback to an Alzheimer's disease cohort by using a combination of both live and

online meetings and questionnaires, free from obligations, works well for this cohort.

What motivates (or demotivates) young adults to participate in longitudinal cohort studies?

by Isabelle Budin-Ljøsne | Rebecca Bruu Carver | Norwegian Institute of Public Health | Norwegian Institute of Public Health

Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation
Presenter Name: Isabelle Budin-Ljøsne
Keywords: biobank, biological samples, longitudinal cohort studies, young adults

Background: Most longitudinal cohort studies find difficult to recruit and retain young adults. The Norwegian Mother, Father and Child Study (MoBa), which follows 95,000 mothers, 75,000 fathers and 114,500 children and adolescents to explore the causes of diseases, is no exception. MoBa is currently experiencing record-low participation among young adults (about 17 % for 18 and 19-year-olds). This study investigated factors that influence the participation of young adults (18-25 years) in longitudinal cohort studies such as MoBa.

Methods: In connection with its 25th anniversary, MoBa recruited a group of young participants to be ambassadors for the study. The ambassadors endorsed the role of researchers and conducted seven face-to-face interviews with peers in their network during the summer of 2024 to investigate their views regarding participation in longitudinal cohort studies, factors motivating or demotivating such participation, preferred forms of participation and research topics of interest. The interviews were recorded, transcribed and reviewed using a qualitative content analysis approach.

Results: Factors influencing motivation to participate in studies included flexibility in the way participation is organized, limited requirements in terms of active contribution through questionnaires and provision of biological samples, relevance of research questions for the young adults' age group, and clear communication regarding research objectives and findings. Factors hindering participation included competing requests from other commercial or non-commercial actors, time-consuming log-in procedures, fears that data and samples may not be used, and lack of trust.

Conclusions: Recruiting and retaining young adults in longitudinal cohort studies require adapting participation processes to their needs.

8D: Connecting Forces: Effective Stakeholder Management

Building Public Trust: Informing 1.3 Million Danes About Their Stored Samples

by Karina Meden Sørensen | Cathrine Hansen | Lydia Viekær | Ruben Bjerregaard Nielsen | Anne-Marie Vangsted | Statens Serum Institut | Statens Serum Institut | Statens Serum Institut | Statens Serum Institut | Statens Serum Institut

Topic: 8D: Connecting Forces: Effective Stakeholder Management
Presenter Name: Anne-Marie Vangsted | Karina Meden Sørensen
Keywords: National legislation, citizens right, sample destruction

Introduction

The Danish National Biobank and the local laboratories at SSI house millions of biological samples collected from both research projects

and diagnostic analyses performed at SSI. All samples are collected in accordance with the applicable legislation, but most citizens were unaware that their samples are stored at SSI, as informing them was not considered a legal obligation prior to 2024. Recently, the Danish Data Protection Agency ruled that all citizens with diagnostic samples stored at SSI must be informed.

Material and methods

Letters were sent to approximately 1.3 million citizens via Danish national electronic post or mail. The letters were sent in bundles according to the types of samples and age groups. Citizens were instructed to contact SSI with questions, requests for access to personal data or sample destruction.

Results

Out of 6 million Danish citizens approximately 1.3 million received a letter regarding storage of their sample. The response rate was 0.2%.

Discussion and conclusion

The response rate was lower than expected, with an anticipated 0.6% based on information letters sent by Copenhagen Hospital Biobank. We distributed letters in three phases, with the highest response in the first phase, likely influenced by a critical TV report and the targeted age group.

Our low response rate reflects a high level of trust in Danish society towards the healthcare system and authorities, while underscoring the importance of transparency, a key objective for SSI. Additionally, the response data offers insights into how the information can be customized for different demographic groups.

Biobank Outreach: Key Challenges and Approaches

by Katia Pozyuchenko | Ayelet Itzhaki-Alfia | Department of Pathology, Division of Research & Development, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel. | Department of Pathology, Division of Research & Development, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel.

Topic: 8D: Connecting Forces: Effective Stakeholder Management

Presenter Name: Katia Pozyuchenko

Keywords: accessibility, collaboration, engagement, strategies, utilization, visibility

Biobanks are an invaluable resource for advancing biomedical research by providing access to vast collections of biological samples along with associated data. Despite their significant contributions, biobanks face several challenges in effectively promoting their potential impact to researchers, healthcare professionals, and the broader public. The TLV Biobank is an integrated healthcare biobank. One of our great challenges is raising visibility of its services, not only among the wider scientific community but also the researchers inside the healthcare. The ability to allocate resources effectively is essential to build engagement strategies and reach the targeted audience.

To address this gap we generated an interface with the existing healthcare data platform to provide an access to de-identified/synthetic data linked to the biobank's cohort for the use of healthcare researchers. In addition, we actively participate in relevant in-house conferences and demonstrate how the biobank contributes to various fields of research. We found that these initiatives have led us to

build strong relationships with researchers and achieve further utilization.

While visibility has fostered utilization, further efforts appear to be needed to maximize the biobank's potential. It is essential to focus on improving accessibility, addressing concerns about ethical guidelines and creating more user-friendly platforms, which will help unlock the full potential of biobanks infrastructure in advancing scientific discovery.

Fostering Biobank Sustainability and Patient Participation through Collaborative Advocacy

by Verena Huth | Ronny Baber | Stefanie Houwaart | Roland Jahns | Cornelia Specht | German Biobank Node (GBN) | Leipzig Medical Biobank (LMB) | BRCA Network – Help for People Affected by Hereditary Cancers (BRCA-Netzwerk e. V.) | Interdisciplinary Biobank and Database Würzburg (ibdw) | German Biobank Node (GBN)

Topic: 8D: Connecting Forces: Effective Stakeholder Management

Presenter Name: Verena Huth

Keywords: Advocacy, Biobank Sustainability, Patient Participation, Political Lobbying, Stakeholder Engagement

Introduction: In 2024, the German Biobank Node and patient organisations published a position paper advocating for better use of centrally organised academic biobanks and stronger patient involvement in research. As patients donate samples to research, they have a fundamental interest in ensuring that their samples are used ethically, transparently and hopefully ultimately for the benefit of their health. This collaborative initiative highlights biobanks as essential partners for reproducible research and safe care.

Material and methods: Findings from a GBN survey revealed limited use of biobanks by researchers. Patient organisations also reported that patient involvement in research remains underdeveloped. The paper was developed through a 12-month participatory process that included web conferences, presentations and stakeholder feedback.

Results: The paper recommends structural reforms, including the integration of biobanks into funding guidelines. It advocates for improved frameworks for sample and data sharing, including the adoption of a 'broad consent' for research purposes. It reflects on how systematic patient involvement can improve research outcomes. The position paper is now being used for scientific advocacy and has been sent to funding organisations and political parties.

Discussion: This initiative serves as a case study in collaborative advocacy and offers lessons for BBMRI-ERIC National Nodes, patient organisations, and biobanks. By emphasising reproducibility, patient engagement, and stable funding, it promotes sustainable research practices and financial stability for biobanks. The dissemination strategy provides a model to influence policy and highlights potential for further initiatives.

Guidance for public involvement and engagement (PPIE) in biobanking

by Eric Vermeulen | Richard Stephens | BBMRI.ERIC Stakeholder Forum | Use MY data, BBMRI.ERIC Stakeholder Forum

Topic: 8D: Connecting Forces: Effective Stakeholder Management
Presenter Name: Eric Vermeulen | Richard Stephens
Keywords: Public and patient involvement and engagement

Background
There are biobanks that involve and engage patients and public, but it is not mandatory and there is no specific guideline for PPIE in biobanking in Europe.

Members of the BBMRI.ERIC Stakeholder Forum initiated the drafting of a guideline, elements of which were discussed with delegates at EBW24. Working with BBMRI-ERIC the patients present the final version to EBW25. The guideline recommends that individual biobanks develop a PPIE policy in cooperation with BBMRI-ERIC and/or their national node.

Discussion
PPIE is important for the accountability and transparency of biobanks. PPIE can be organised along different levels of participation, from 'informing' the public about biobanking via 'consulting' and 'involving' to 'collaborating' and ultimately 'empowering' members of the public to collaborate with biobankers. Biobanks can involve representatives structurally in governance committees as steering and oversight committees, in advisory groups, or in ad-hoc ways through consultations, surveys, interviews, focus groups and workshops. The guideline describes methods, examples and tools that biobanks can use to implement PPIE.

Conclusion
This patient-led guideline for PPIE enables biobanks to develop a PPIE strategy. It expresses the wish of the BBMRI-ERIC/ESBB community, and especially the request from patient organisations, that biobanks consider, organise and embed the engagement and involvement of the public in their work. The document shows how different forms of involvement can be organised. Biobanks should now either develop PPIE or justify why they do not do it.

10D: Emerging EU Regulations Unveiled: Latest ELSI Developments and National Perspectives

Interplay between the Belgian biobank legislation and EU level CTR, MDR/IVDR regulations

by Pieter Moons | Biobank Antwerpen
Topic: 10D: Emerging EU Regulations Unveiled: Latest ELSI Developments and National Perspectives
Presenter Name: Pieter Moons
Keywords: CTR, ELSI, MDR/IVDR, biobank legislation

Introduction
Belgium has an extensive and complex biobank legislation requiring:

- Full traceability of all human body material (HBM) and derivates thereof used in research.
- Contracts with a biobank for every use of the samples.

Studies under CTR are excluded from the biobank legislation, though samples remaining for secondary use are included. Studies under MDR/IVDR are included.

Questions

- How do sponsors now about the interplay between Belgian biobank legislation and CTR?

- How to define secondary use in view
- of studies under CTR?
- What about companion diagnostics under MDR/IVDR for a study under CTR?

  Can workflows and documents be developed that inform sponsors and ethics committees?

Results

Multistakeholder effort including BAREC (Belgian Association of Research Ethics Committees), CT college (governing CTR studies), FAGG (government) with input from BBMRI.be, pharma.be and experts from ethics committees and clinical trial centers resulted in:

- Development of EU level template on HBM, meanwhile endorsed by CTEG and approved by the European Commission.
- Definition on secondary use included in a dedicated section in this template + made it mandatory in Belgium informing both sponsors and ethics committees.
- Phrasing reflected in national ICF templates made obligatory for all CTR studies in Belgium
- Companion diagnostics under MDR/IVDR excluded from Belgian biobank legislation in case of detailed description in CTR protocol.

Conclusions

Bringing together all stakeholders resulted in a streamlined workflow and supportive documents informing sponsors and study evaluators and bridging legal developments on a national and international level.

Challenges for Biobanks under the EHDS Regulation's introduction of opt-out as a standard form of individuals' participation in the use of their data

by Schlünder, I. | BBMRI ERIC

Topic: 10D: Emerging EU Regulations Unveiled: Latest ELSI Developments and National Perspectives

Presenter Name: Schlünder, I.

Keywords: EHDS Regulation, informed consent, opt-out

Article 71 EHDS Regulation provides the EU wide right to opt out from the processing of personal electronic health data for secondary use; the implementation of the opt out system is left to the Member States. This raises many questions for those usually having been collecting data on the basis of informed consent as it is true for biobanks. The questions are: Will the Regulation establish the obligation for biobanks to grant access to the data from donors according to procedure and rules of the EHDS infrastructure irrespective of the limitations of the provided consent? If yes, is there an obligation to inform donors about the fact that their data will be used in future in this way in order to provide them with the possibility to withdraw their consent and request the deletion of their data, if they disagree with data sharing through EHDS? Are biobanks obliged to inform about the right to opt-out? Can the opt-out declaration of individuals be limited to certain data sources? Or to certain types of data, e.g. genomic data? How and by whom is the opt-out decision been executed? If these questions are left to Member State legislation or practice, how much fragmentation lies ahead?

EHDS implications for biobanks as data holders and data users

by Erdina Ene | BBMRI-ERIC

Topic: 10D: Emerging EU Regulations Unveiled: Latest ELSI Developments and National Perspectives

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Keywords: EHDS, biobank, data holder, data user, health data

The implementation of the EHDS in the EU area will impact the way patients' data is further used for research purposes. Biobanks are a very valuable source of health data, but nonetheless not explicitly mentioned in the EHDS. As a result, understanding what the EHDS's impact on biobanks will be is an important path to go through. For this to happen, the dual nature of the biobanks needs to be analyzed. Biobanks as data holders are implicated when mentioning them as one of the minimum categories of health data that have to be made available for secondary use (Article 51). What about biobanks as data users? Does article 53 legitimize their nature as such? What will change for EU based biobanks after the implementation of the EHDS? Taking into account the substantial effect EHDS has had in legislations beyond the EU, will other biobanks be affected as well?

A dive Into these questions might help to have a better grasp of the "new era" biobanks and as a further step to think of a separate legislation that will mirror these changes.

European Health Data Space – the current state of affairs in the Netherlands

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The European Health Data Space (EHDS) makes it possible to share health data on a national and European level for primary and secondary use. The aim of the EHDS is to arrange better care through data availability.

The Ministry of Health, Welfare and Sport developed the Dutch National Vision and Strategy (NVS) on the Health Information System. The basic principle of the NVS is that the necessary medical data is available to use for health, prevention and/or care.

Health-RI serves as the national coordination point for agreements on the reuse of health data and is closely involved in the development of the EHDS, particularly in the field of secondary use of health data. Health-RI's mission is to achieve better health(care) for citizens and patients by reusing health data with an integrated health data infrastructure for research, policy and innovation.

Health-RI actively collaborates with the Ministry of Health, Welfare and Sport and many stakeholders in the Netherlands and Europe to gain a clear picture of interests and shape the implementation of the regulation in the Netherlands.

From the NVS, we are working on many components that collectively lay the foundation for the health information system that is necessary to continue to provide high-quality, accessible and affordable care now and in the future.